Supreme Court, U.S.
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No. 97-

IN THE

Supreme Court of the United States

OCTOBER TERM, 1997

ROBERT L. HESS,

Petitioner,

v.

ADVANCED CARDIOVASCULAR SYSTEMS, INC.,

Respondent.

ADVANCED CARDIOVASCULAR SYSTEMS, INC.,

Respondent,

v.

SCIMED LIFE SYSTEMS, INC.,
and
ROBERT L. HESS,

Petitioner.

Petition for a Writ Of Certiorari to the United States Court of Appeals for the Federal Circuit

PETITION FOR A WRIT OF CERTIORARI

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28 pp

QUESTION PRESENTED

Did not the Federal Circuit err in finding that a claimant had failed to establish that the claimant was a co-inventor of the subject matter of a patent issued to two named inventors where:

(a) It was undisputed in the record below that the claimant made three contributions to the subject matter of the patent, each one of those contributions being recited in one or more claims of the patent;

(b) Each of the contributions admittedly made by the claimant were referenced among the objects of the invention and at least two of those three contributions were relied upon during the prosecution of the patent to distinguish the subject matter thereof from the prior art;

(c) Both named inventors conceded that, before they met with the claimant, neither was able to develop an operative embodiment of the invention;

(d) The Federal Circuit brushed aside precedent that has been followed for over 80 years—precedent that formed the basis for the 1984 Amendment to the Patent Statutes governing inventorship; and

(e) The Federal Circuit intertwined findings of fact made by the District Court with its conclusion of law, giving deference to the District Court's conclusions of law as though they had been findings of fact.

PARTIES TO THE PROCEEDING

Petitioner is Robert L. Hess, an individual.

Respondent is Advanced Cardiovascular Systems, Inc.

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PETITION FOR A WRIT OF CERTIORARI

Robert L. Hess ("Hess") respectfully petitions for a Writ of Certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit.

OPINIONS BELOW

The Federal Circuit's judgment and opinion, reported at 106 F.3d 976 (Fed. Cir., 1997), are reproduced in Appendix A (App. A) at 1a. The judgment and oral opinion of the United States District Court for the Northern District of California are unreported and are reproduced at App. A 16a.

JURISDICTION

The District Court had jurisdiction under 28 U.S.C. §§ 1331 and 1338(a). The judgment of the Court of Appeals was entered on February 18, 1997. This Court has jurisdiction to issue the writ under 28 U.S.C. § 1254(1).

STATUTE INVOLVED

Section 116 of the Patent Act of 1952, 35 U.S.C. § 116, provides in pertinent part:

> "When an invention is made by two or more persons jointly, they shall apply for patent jointly and each make the required oath, except as otherwise provided in this title. Inventors may apply for a patent jointly even though (1) they did not physically work together or at the same time, (2) each did not make the same type or amount of contribution, or (3) each did not make a contribution to the subject matter of every claim of the patent."

STATEMENT OF THE CASE

In this case, the Court of Appeals for the Federal Circuit ruled that Robert L. Hess was not a co-inventor of the patent-in-suit, even though, as the District Court had found, the inventors named in the patent did not dispute that Hess had made three of

the four contributions he alleged that he had made, those three contributions having been found throughout the claims of the patent-in-suit. Indeed, so important was one contribution that it was singled out by one of the named inventors in a medical publication as one of the two reasons underlying the success of the invention. On top of that, that very contribution served as a basis to distinguish claims of the patent from the prior art. Nonetheless, both the District Court and the Court of Appeals concluded, in applying the law to those undisputed facts, that Hess' contributions were not of sufficient fundamental importance to warrant his being named as a co-inventor of the subject matter of the claims.

In so ruling, the Court of Appeals brushed aside as not binding on it, an old decision by the United States District Court for the District of New Jersey, later affirmed by the Court of Appeals for the Third Circuit. What the Court of Appeals for the Federal Circuit overlooked, however, was the fact that the legislative history of the controlling statute, 35 U.S.C. § 116, had roots going back to the very District Court decision which the Court of Appeals for the Federal Circuit had brushed aside.

I. *The Background Facts*

A. *The Parties And The Cause Of Action*

The present controversy first began when respondent, Advanced Cardiovascular Systems, Inc. ("ACS"), brought suit in the District of Minnesota in March of 1987, seeking damages and injunctive relief for the alleged infringement of United States Patent No. 4,323,071 ("the '071 patent", App. B 1b)* which issued on April 6, 1982 to Dr. John B. Simpson and Dr. Edward W. Robert. ACS is a manufacturer of angioplasty

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*For the Court's convenience, the patent and reexamination certificate are reproduced in Appendix B (App. B).

catheters for use in treating diseases of the heart, to which the '071 patent is directed.

Named as the defendant was Scimed Life Systems, Inc., an ACS competitor who manufactured angioplasty catheters accused of infringing the '071 patent. Among other grounds, Scimed defended ACS' charge of infringement by alleging that Robert L. Hess, an engineer employed by a plastic supplier known as Raychem Company, had assisted Simpson and Robert in the development of the patented catheter, and hence was a co-inventor of the '071 patent. Thus, Scimed pleaded invalidity based on the failure to include Hess as an inventor of the '071 patent.

In August of 1990, Hess intervened in the *ACS* v. *Scimed* litigation, filing a cross-complaint seeking a declaration that he was a joint inventor along with Simpson and Robert of the subject matter claimed in the '071 patent. The District Court in Minnesota dismissed Hess' cross-claim on a laches theory, and Hess appealed to the Court of Appeals for the Federal Circuit in January of 1992. While Hess' appeal was pending, Hess filed an original action in the Northern District of California alleging that he was a co-inventor of the claims added to the '071 patent during reexamination proceedings under 35 U.S.C. § 305. The underlying litigation between ACS and Scimed settled, but Hess pursued his appeal from the Minnesota Court's dismissal of his cross-claim. After the Court of Appeals for the Federal Circuit reversed that dismissal (*Advanced Cardiovascular Systems, Inc.* v. *SciMed Life Systems, Inc. and Robert L. Hess* (Fed. Cir., 1993), 988 F.2d 1157), the case was remanded to Minnesota and was thereafter transferred to the Northern District of California where it was consolidated with Hess' original action brought there.

During the District Court proceedings, ACS filed motion after motion, seeking to dismiss Hess' inventorship claim. And the District Court repeatedly denied those motions. Finally, on

the eve of trial, the District Court granted an ACS motion to dismiss, grounded on a laches theory, that part of Hess' claim seeking a determination of co-inventorship of original claims 1-21 of the '071 patent. The District Court set for trial the remaining issues of Hess' claim of co-inventorship as to those claims added to the patent in May of 1990 by way of the reexamination proceeding, namely claims 22-52.

B. *The Evidence At Trial*

In early 1978, Hess met with two cardiologists at Stanford University who were seeking assistance in the design of a catheter for balloon angioplasty, namely Dr. John B. Simpson and Dr. Edward W. Robert. Simpson, having seen an angioplasty catheter in Europe found to be in short supply, decided to build, with Robert, a catheter of their own. Hess had been recommended to Simpson and Robert as having some expertise in working with plastics.

At the time that Simpson and Robert met with Hess, they were at a complete loss as to what material might be suitable for use in making an angioplasty catheter, having been unsuccessful in their previous attempts to employ polyvinyl chloride (PVC), the material that Dr. Gruntzig had used in Europe, and also having been unsuccessful with Teflon plastic. Simpson testified (App. A 36a):

> "Q. You had tried two different plastic materials and you were not successful with either one of them.
>
> "A. That's right."

Dr. Robert was equally pessimistic (App. A 48a-49a):

> "Q. In fact, the only two materials that you had worked with to speak of were Teflon and PVC, and neither one of those met your needs; isn't that correct?
>
> "A. Neither one was optimal.

"Q. In fact, they didn't meet your needs at all, did they?

"A. To the extent that we carried them, no they did not."

In fact, both men conceded that, at the time they first met with Hess, neither had the correct material to achieve the result that either was seeking. Simpson acknowledged (App. A 46a):

"Q. Okay. And so really where you were at the time you met Mr. Hess was you knew where you wanted to go, but you didn't have any way until Hess came along to get there.

"A. We didn't have the right material to get there. That's correct."

Robert's testimony was essentially the same (App. A 48a):

"Q. . . . Wouldn't it be accurate to say that at the time just prior to the time that you hooked up with Mr. Hess, that you knew what you wanted, but you didn't know how to get there in terms of the materials?

"A. We were—we were uncertain as to what the optimal material would be at that time, that's correct."*

At that first meeting, Simpson described the Gruntzig catheter with its tubular shaft closed at one end having a small hole in the shaft near that end. A balloon formed as a separate element was placed over the shaft, covering the small hole to permit a radiographic fluid to be pumped through the shaft and through the hole into the balloon causing the balloon to expand.

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*Hess, at the time, served as a technical liaison between Raychem's United States operation and its international operations in South America and Asia.

Simpson and Robert told Hess that their first task was to find a material suitable for use in fabricating the balloon. Hess suggested that they employ one of Raychem's many plastics known as irradiated modified polyolefins which could be heat shrunk to any desired dimension. Indeed, during their first meeting, Hess demonstrated, using a Raychem irradiated modified polyolefin, how that material could be heat shrunk at both ends leaving a balloon between them.

Later on, Hess also suggested that the balloon itself could be shrunk fit onto the central lumen or tube of the catheter to permit the balloon to be attached to that central lumen without the use of an adhesive (App. A 37a-38a):

> "A. . . . So we contacted Mr. Hess, and asked him for some advice on how to improve the adhesives. And he said he would just leave the adhesives out.
>
> "Q. So would you agree that Mr. Hess made a contribution to the catheter in respect to the use of shrink fitting without the use of an adhesive in the distal end?
>
> "A. Yeah, I would agree that he gave us some advice on—on what we could do about the adhesive-related problem that we having were at the distal tip of the catheter."

As the District Court found, the parties were in agreement that Hess made three of the four contributions to the final catheter design that Hess claimed that he made:

(1) Hess suggested the use of irradiated modified polyolefins as the material from which the balloon should be fabricated—a material which both Simpson and Robert were totally unfamiliar with at the time;

(2) Hess suggested that the balloon could be formed by heating a portion of the irradiated modified polyolefin tubing to a temperature above its crystalline melting point and then applying pressure to expand the tubing to preform the balloon; thereafter, the balloon could be cooled to a temperature below its crystalline melting point at which it retained its expanded shape; and

(3) Hess suggested the use of an adhesive-free seal at the distal end of the catheter to avoid the use of toxic adhesive chemicals, suggesting instead that the outer tubing in which the balloon was formed be simply shrink fitted onto the inner lumen to form an adhesive-free seal.*

C. *The Simpson-Robert Patent Application — Quietly Filed*

On April 24, 1978, Simpson and Robert filed an application for patent on the catheter developed during their collaboration with Hess. Unaccountably, however, there was no proof at the trial that Hess was told that the application had been filed.

In describing the invention, however, Simpson and Robert made liberal references to the information Hess had admittedly supplied to them. The objects of the invention were replete with references to Hess' suggestions, including his suggestion that irradiated modified polyolefins be used to form the balloon. The patent says (App. B 6b, col. 2, ll. 35 *et seq.*):

> "Another object of the invention is to provide a dilating catheter assembly of the above character in which the catheter is formed of an irradiated modified polyolefin tubing."

*Hess had also urged at the trial that he suggested the coaxial concept of providing an annular space between the balloon and the inner lumen through which radiographic fluid could be supplied to inflate the balloon. Hess' contribution in that regard was the only one disputed at the trial.

Equally prominent among the objects of the invention was Hess' suggestion that the outer tube from which the balloon was formed be heat shrunk onto the inner tubing to form an adhesive-free seal (App. B 6b, col. 2, ll. 39 *et seq.*):

> "Another object of the invention is to provide a dilating catheter assembly of the above character in which inner and outer coaxial tubular members are provided and in which a distal pressure seal is formed between the inner and outer tubular members solely by heating the outer heat shrinkable tubular member."

The specification also taught the balloon fabrication technique that Hess suggested, namely the heating of the irradiated modified polyolefin to temperatures above its crystalline melting point followed by the application of pressure and cooling to form the balloon (App. B 8b, col. 5, ll. 15 *et seq.*).*

There was no debate in the District Court that the subject matter of Hess' contributions were reflected in the claims of the '071 patent. Claim 22 (App. B 17b), as an example, refers to the technique of forming the balloon out of a crystalline plastic material by heating it to a temperature above its crystalline melting point, after which pressure is applied and the balloon then cooled. Simpson flatly admitted that claim 22 embodies Hess' contributions (App. A 44a):

> "Q. Now, that [claim 22] describes a technique in general terms of how the balloon can be made, correct?
>
> "A. That's correct.

*That patent application formed the basis for Simpson's and Robert's organization of Advanced Catheter Systems, a company that thereafter became Advanced Cardiovascular Systems, Inc. Until recently, ACS was a wholly owned subsidiary of Eli Lilly and Company.

"Q. And it also describes in general terms information that Mr. Hess supplied to you, does it not?

"A. That's correct, uh-huh."

Dr. Simpson likewise conceded that the claims also embody Hess' suggestions of the adhesive-free seal at the distal end of the catheter (App. A 40a):

"Q. . . . You were trying to put an adhesive in that area, weren't you?

"A. We had put an adhesive in that area.

"Q. Right. Mr. Hess said: No, don't do that.

"A. That's right, he did. Absolutely. Nondisputed.

"Q. You adopted his suggestion and you put that suggestion in claim 13 of your patent, didn't you?

"A. It shows up here, yes. Uh-huh."

Hess' contributions pervade the claims of the '071 patent.

D. *The ACS Litigation With Scimed And The Reexamination Proceedings*

During its litigation with ACS, Scimed, apart from its invalidity plea based on the failure to join Hess as a co-inventor, argued that at least some of the claims of the '071 patent were invalid in light of prior art patents. As a result, two requests for reexamination of the '071 patent were filed during the litigation.

During the reexamination proceedings, ACS submitted a declaration of Dr. Simpson aimed at establishing that the subject matter of the '071 claims was not obvious in light of prior art teaching a natural rubber balloon. ACS said that such a balloon would inflate in an uncontrolled manner compared to irradiated modified polyolefin balloons described in the patent—the very material that Hess had recommended. At trial, Dr. Simpson readily agreed that one of the points he was seeking to make in his declaration (App. A 56a-58a) was to distinguish the prior art on the basis of his use of an irradiated modified polyolefin (App. A 42a):

> "Q. And one of the points that you made, Dr. Simpson, as to how there was a difference, was that the '873 patent used a balloon made of a stretchable material, such as natural or synthetic rubber; correct?
>
> "A. That's correct.
>
> "Q. And your point was that: I look at our invention; we're using an irradiated modified polyolefin, and that doesn't expand in an uncontrolled manner; whereas this '873 patent is using a natural or synthetic rubber balloon, and that can expand in an uncontrolled manner. Wouldn't you agree?
>
> "A. I certainly would agree.
>
> "Q. Okay. And so that was—that was a difference that you were pointing out between the material of construction that you used; namely, the irradiated modified polyolefin, versus the material of construction that the '873 patent used; namely, natural or synthetic rubber.
>
> "A. That's correct."

Hess' contribution—the use of irradiated modified polyolefins to make balloons—played a prominent role when ACS distinguished its patented catheter from the prior art.*

II. *The Decisions Below*

A. *The District Court*

The District Court, after briefing and argument by the parties, issued an oral decision from the bench (App. A 20a). The District Court, to its credit, correctly articulated the test of co-inventorship (App. A 23a-24a):

> "...I think that all Mr. Hess needs to establish is that he conceived some important element or some important claim that is claimed in the patent, and need not have sat down and says here is what the whole device is going to look like when we're finished.
>
> * * *
>
> So, I don't think it's necessary for Mr. Hess to conceive of every feature of the catheter, but that if some conceptual role in at least an important or a necessary element, or important and necessary claim."

The District Court went on to note that inventors can utilize the services and ideas of others without losing their status of inventorship. The important question in determining inventorship is who participated in the conception of the invention claimed (App. A 24a).

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*Long before this controversy arose, Simpson wrote a paper (App. A 50a) crediting the success of his catheter to two features—the coaxial design and the use of "unique materials" (App. A 51a). There was no dispute that the "unique materials" to which Dr. Simpson referred were the irradiated modified polyolefins Hess had suggested.

In this case, the District Court noted that the evidence, for the most part, was not in dispute (App. A 27a):

> "In fact, I find very few conflicts on the key points in this case, and that is, what did Mr. Hess do with respect to this invention.
>
> Mostly the issue comes down to conclusions of fact or conclusions of law to be drawn from the facts that the witnesses were really not debating about."

The District Court concluded that Hess' contributions were not inventive contributions. While agreeing that the three contributions were not in dispute, the District Court ruled that Hess' role was not that of an inventor (App. A 29a-30a):

> "It may have a certain degree of ingeniousness to it, but that is not inventorship. That is, Raychem had this product. Heat-shrink tubing was on the market. It may not be known to Simpson and Robert, but it was a product Raychem had been making and somebody knew about it.
>
> * * *
>
> So when they were meeting with Mr. Hess, I think what Mr. Hess was doing was showing them available product, telling them its properties, telling them how it could be used, and how it might be used."

The District Court also concluded that a Simpson-Robert letter (App. A 53a-55a) defined Hess' role respecting the catheter disclosed in the '071 patent "as well as anybody could define it" (App. A 28a). As the District Court observed, that letter expressed (App. A 29a):

> "... clearly some debt of gratitude at least by Simpson and Robert to Mr. Hess, albeit I'm finding that that is not a debt that rises to a level of being a coinventor."

On that basis, the District Court rejected Hess' plea that he was a co-inventor of the '071 patent.

B. ***The Decision Of The Court Of Appeals***

Hess took his appeal from the District Court's judgment to the United States Court of Appeals for the Federal Circuit. The Court of Appeals, on February 18, 1997, affirmed the District Court with a written opinion (App. A 2a).

Where the Court of Appeals went astray was in its conclusion that Hess' argument before it to the effect that the District Court had misapplied the appropriate test of inventorship was an argument that the District Court's factual findings were clearly erroneous (App. A 12a):

> "Mr. Hess argues, however, that the court 'completely misapplied' that standard 'in finding that Hess's contributions were not inventive.' This argument, however, is in reality only a reformulation of the contention that the district court's findings upon which the court based its conclusion that Mr. Hess had not established co-inventorship, are clearly erroneous."

The Court of Appeals lost sight of the distinction between the fact findings by the District Court, namely that Hess had indeed made the contributions of (1) suggesting an irradiated modified polyolefin, (2) suggesting the technique claimed for forming the balloon and (3) suggesting an adhesive-free seal at the distal end of the catheter, and the conclusions of law based on those findings. The District Court, after all, found that Hess' three contributions were indeed undisputed, and based its decision on its own conclusions of law flowing from Hess' three undisputed contributions. In that respect, the Court of Appeals failed to follow its mandate as an appellate court in reviewing factual findings under a clearly erroneous standard and conclusions of law *de novo.*

The Court of Appeals dismissed altogether Hess' reliance on the famous old case of *DeLaski & Thropp Circular Woven Tire Co.* v. *William R. Thropp & Sons Co.* (D.N.J., 1914), 218 F. 458, 464, aff'd. (3rd Cir., 1915), 226 F. 941 where the Court had laid down a time-honored test of inventorship:

> "The conception of the entire device may be due to one, but if the other makes suggestions of practical value, which assisted in working out the main idea and making it operative, or contributes an independent part of the entire invention, which is united with the parts produced by the other and creates the whole, he is a joint inventor, even though his contribution be of comparatively minor importance and merely the application of an old idea."

Unaccountably, the Court of Appeals overlooked the fact that *DeLaski*, treated by the Court of Appeals as "not binding precedent" before it (App. A 14a), formed the basis for the legislative history of the 1984 amendments to 35 U.S.C. § 116, the statutory provision defining joint inventorship. Upon that basis, the Court of Appeals affirmed the District Court's holding that Hess had failed to establish co-inventorship.

REASONS FOR GRANTING THE PETITION

This case presents a question going to the very heart of the patent system, namely, what acts are necessary to satisfy the joint inventorship requirements of 35 U.S.C. § 116. Indeed, the determination of inventorship is a threshold question, preceding in almost every instance the filing of an application for a patent in the first instance. This Court has stressed the importance of the Federal Circuit considering—and definitively settling—patent law issues (*Cardinal Chemical Company* v. *Morton International, Inc.* (1993), 508 U.S. ____, ____, 113 S.Ct. 1967, 1971). Consequently, what the Federal Circuit does in a precedent-setting case like this one is a matter of "special importance" to the United States.

In this case, Hess was a good Samaritan, offering his assistance to the named inventors who themselves characterized Hess' assistance contemporaneously (App. A 53a):

> "After weeks of frustration because of unsuccessful attempts to obtain assistance or advice from any of the Bay Area plastics firms, we were introduced to Mr. Rob Hess. His advice, frequently requested at unusual hours and often interrupting his weekend at home, has been tireless and critically important to our progress."

Drs. Simpson and Robert added (App. A 53a):

> "Rob introduced us to Raychem modified irradiated polyolefins, suggested numerous approaches to construction, searched diligently for special extrusions that would meet our dimensional requirements, and provided us with more than sufficient samples to construct our prototypes. All of this was done with a genuinely concerned and helpful attitude which has made our brief association with Raychem exciting and productive, and most importantly, it has led to what we consider a device which may well revolutionize the treatment of coronary artery disease in the United States."

Not only did Drs. Simpson and Robert make a contemporaneous admission that Hess' assistance was "critically important" to their progress, the trial record showed without any dispute that both, at the time they first met Hess, had failed to fabricate a balloon for their catheter. And, of course, it should also not be forgotten that both conceded that Hess' admitted contributions found their way into the claims of the patent. It defies reason to conclude, as did the Courts below, that Hess was anything but a co-inventor and the conclusion of the Court of Appeals to the contrary was simply based on a misapprehension of inventorship law, engendered in the first instance by the Federal Circuit's rejection of a time honored legal precedent which even the Court of Appeals seemed to acknowledge would have compelled a different result.

I. *The Federal Circuit Applied An Erroneous Legal Standard In Concluding That Hess Was Not A Co-Inventor*

A. *The Legislative History Of 35 U.S.C. § 116 Was Based On The Very Precedent The Federal Circuit Rejected*

Since the adoption of the Patent Act in 1952, Section 116 has always governed joint inventorship (35 U.S.C. § 116). Prior to its amendment in 1984, § 116 provided, in pertinent part:

> "When an invention is made by two or more persons jointly, they shall apply for patent jointly and each sign the application and make the required oath, except as otherwise provided in this title."

The identity of the inventors in either a patent or an application therefor is of enormous importance. Under 35 U.S.C. § 111, except in special circumstances not present here, an application for patent shall either be made or authorized to be made by the inventor or inventors thereof. Indeed, that requirement of the patent statute is a constitutionally-mandated requirement; Article I, § 8 of the Constitution authorizes Congress to grant an exclusive right in discoveries to inventors and none other (*Iowa State University Research Foundation, Inc.* v. *Sperry Rand Corporation* (4th Cir., 1971), 444 F.2d 406, 408).*

The determination of inventorship is critically important for yet another reason, namely ownership of the patent. The grant of

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*Congress recognized, in 1952, the difficulty in determining inventorship and, as part of the Patent Act, promulgated § 256 to allow for correction of errors in inventorship to avoid forfeiture of valuable patent rights. 35 U.S.C. § 256 allows the correction of inventorship in an issued patent; it requires a showing of an "error" if a person is either incorrectly named in an issued patent or omitted as an inventor in an issued patent, provided that the error arose "without any deceptive intention". In that limited situation, an error in inventorship, under the express terms of § 256, does not invalidate the patent so long as the error can be corrected under § 256. 35 U.S.C. § 116 contains a like remedial provision, permitting correction of "error" in inventorship in an application for patent; it limits such correction to those errors which arose without any deceptive intention as well.

a patent is made, consistent with the Constitution, to an inventor in the absence of an assignment. And, of course, each of the inventors of a patent who have not made an assignment of his or her rights thereunder is entitled, under 35 U.S.C. § 262, to make, use, offer to sell or sell the patented invention "without the consent of and without accounting to the other owners" (*Willingham* v. *Lawton* (6th Cir., 1997), 555 F.2d 1340, 1344).

Because of the importance of properly determining joint inventorship and the difficulties attendant thereto, Congress, in 1984, amended 35 U.S.C. § 116. That amendment continued to limit application of the statute to cases where an invention was made by two or more persons "jointly" but also added the following guidelines as to joint inventorship:

> "Inventors may apply for a patent jointly even though (1) they did not physically work together or at the same time, (2) each did not make the same type or amount of contribution, or (3) each did not make a contribution to the subject matter of every claim of the patent."

The Federal Circuit recognized, in *Kimberly-Clark Corporation* v. *Proctor & Gamble Distributing Co., Inc.* (Fed. Cir., 1992), 973 F.2d 911, 916-17, that the legislative history of the 1984 amendment to 35 U.S.C. § 116 demonstrated that Congress intended to clarify the law of joint inventorship by codifying the principles stated in *Monsanto* v. *Kamp* (D.D.C., 1967), 269 F.Supp. 818, 824 where the Court laid down the governing principles:

> "To constitute a joint invention, it is necessary that each of the inventors work on the same subject matter and make some contribution to the inventive thought and to the final result. Each needs to perform but a part of the task if an invention emerges from all of the steps taken together.... One may do more of the experimental work while the other makes suggestions from time to time. The fact that each of the inventors plays a different role and that

> the contribution of one may not be as great as that of another, does not detract from the fact that the invention is joint, if each makes some original contribution, though partial, to the final solution of the problem."

And, of course, those principles laid down in *Monsanto,* later codified in § 116, came directly from the very precedent which the Federal Circuit cavalierly dismissed as "not binding" on it, namely *DeLaski & Thropp Circular Woven Tire Co.* v. *William R. Thropp & Sons Co.* (D.N.J., 1914), 218 F. 458, *aff'd.*, (3rd Cir., 1915), 226 F. 941. The Court in *DeLaski* wrote (218 F. at 464):

> "The conception of the entire device may be due to one, but if the other makes suggestions of practical value, which assisted in working out the main idea and making it operative, or contributes an independent part of the entire invention, which is united with the parts produced by the other and creates the whole, he is a joint inventor, even though his contribution be of comparatively minor importance and merely the application of an old idea."

The Federal Circuit implicitly recognized that *DeLaski* demanded a different result here. Beyond dispute was the fact that Hess, in making the three contributions all hands agree that he in fact made, assisted in "working out the main idea and making it operative". Indeed, the testimony of Simpson and Robert showed on its face that, prior to meeting Hess, neither of them could work "out the main idea and make it operative". Not only were Hess' contributions essential for making the catheter operative, those contributions pervaded the patent claims.

Clearly, under the law, Hess was a co-inventor, and the Federal Circuit's conclusion to the contrary ignored the words of the statute, its legislative history and, indeed, even its own precedent interpreting that legislative history. Not only was Hess a co-inventor, so too he was entitled to an undivided one-third interest in the invention of the '071 patent as well.

B. *Wrong Was The Court Of Appeals In Finding That* DeLaski *Is Inconsistent With Precedent Of This Court*

The Court of Appeals for the Federal Circuit was unduly concerned that *DeLaski* is inconsistent with the decision of this Court in the famous telegraph case, *O'Reilly* v. *Morse* (1853), 56 U.S. 62. Even the suggestion of an inconsistency demonstrates clear legal error in the Federal Circuit's analysis.

DeLaski has been followed for the last 80 years, and holds that a person who makes a suggestion of "practical value" which "assisted in working out the main idea and making it operative" is a joint inventor (218 F. at 464):

> "... even though his contribution be of comparatively minor importance and merely the application of an old idea."

What should control, in determining co-inventorship, is the impact that such a person's contribution has on the making of the invention, and not on whether his idea was, in any abstract way, known in the prior art.

The Federal Circuit's misconception of *O'Reilly* is highlighted by its reliance on its own precedent of *Shatterproof Glass Corporation* v. *Libby-Owens Ford Company* (Fed. Cir., 1985), 758 F.2d 613, 624 where the Court stated that:

> "An inventor 'may use the services, ideas, and aid of others in the process of perfecting his invention without losing his right to a patent.' "

The Federal Circuit's view of *O'Reilly* and *Shatterproof* confuses the vital distinction between a suggestion made by a third party after an operative invention has been conceived, as was the case in both *O'Reilly* and *Shatterproof*, and the case here where Hess' suggestions made possible the conception of an operative invention. After all, Hess admittedly suggested the use of irradiated

modified polyolefins, the plastic that Simpson and Robert ultimately used after their earlier efforts with both PVC and Teflon had failed so miserably.*

II. *The Federal Circuit Improperly Understood Its Role As A Reviewing Court*

Elementary is the principle that, as an Appellate Court, the Federal Circuit's job is to review fact findings as prescribed by Rule 52(a) of the Federal Rules of Civil Procedure, under the "clearly erroneous" standard. But its review of the conclusions of law drawn therefrom—the application of the law to the facts—is reviewed under completely different standards, namely *de novo* review (*Kimberly-Clark Corporation* v. *Proctor & Gamble Distributing Co., Inc.* (Fed. Cir., 1992), 973 F.2d 911, 915; *Roton Barrier, Inc.* v. *Stanley Works* (Fed. Cir., 1996), 79 F.3d 1112, 1127).

In this case, the District Court's fact findings were not even placed in issue, the underlying facts—what did Hess do with respect to the invention of the '071 patent—not being in dispute. What Hess did challenge in the Court of Appeals was the District Court's analysis—how the law should be applied to the facts as found by the District Court. The Federal Circuit muddled that distinction, stating (App. A 12a) that Hess' argument was only a "reformulation" that the District Court's fact findings were clearly erroneous—a plain mischaracterization of Hess' position.

And these issues are indeed important issues in the field of patents. As shown, issues of joint inventorship could arise in virtually every patent issued by the United States Patent Office. It

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*The Federal Circuit, contrary to *DeLaski*, made much of the fact that irradiated modified polyolefins and their properties were known in the prior art—a proposition that Hess certainly does not dispute. What the Federal Circuit failed to note, however, was that it was undisputed that such plastic had never before been used in a medical instrument for use inside the human body. And, of course, the Federal Circuit overlooked as well the undisputed fact, admitted by Dr. Simpson, that the use of irradiated modified polyolefins provided a basis for distinguishing the invention from the prior art.

was incumbent upon the Court of Appeals for the Federal Circuit to lay down guidelines on that issue, guidelines determined in the first instance by the words of the statute and its legislative history as well as by established precedent. In this case, however, the Court of Appeals ignored the language of the statute, ignored its legislative history and failed to follow its own precedent in interpreting the statute in light of the legislative history as established in *Kimberly-Clark Corporation* v. *Proctor & Gamble Distributing Co., Inc.* (Fed. Cir., 1992), 973 F.2d 911.

Because of the importance of this issue, this Court should step in and define, the Federal Circuit having defaulted on its obligation to do so, the principles applicable in determining joint inventorship.

CONCLUSION

Hess' petition is meritorious and should be granted.

Respectfully submitted,

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Supreme Court, U.S.
FILED

(2)

No. 96-1857 MAY 19 1997

OFFICE OF THE CLERK

IN THE

Supreme Court of the United States

OCTOBER TERM, 1997

ROBERT L. HESS,

Petitioner,

v.

ADVANCED CARDIOVASCULAR SYSTEMS, INC.,

Respondent.

ADVANCED CARDIOVASCULAR SYSTEMS, INC.,

Respondent,

v.

SCIMED LIFE SYSTEMS, INC.,
and
ROBERT L. HESS,

Petitioner.

Petition for a Writ Of Certiorari to the United States Court of Appeals for the Federal Circuit

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APPENDIX A

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59 pp

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

96-1066

ROBERT L. HESS,
Plaintiff-Appellant,
v.
ADVANCED CARDIOVASCULAR SYSTEMS, INC.,
Defendant-Appellee.

ADVANCED CARDIOVASCULAR SYSTEMS, INC.,
Plaintiff/Cross-Complainant Defendant-Appellee,
v.
SCIMED LIFE SYSTEMS, INC.,
Defendant,
and
ROBERT L. HESS,
Cross-Complainant/Appellant.

JUDGMENT

Appeal from a decision of the United States District Court for the Northern District of California in 92-CV-1956 and 93-CV-3438 entered September 1, 1995, Judge Charles A. Legge.

This CAUSE having been heard and considered,

it is ORDERED and ADJUDGED: *AFFIRMED*

ENTERED BY ORDER
OF THE COURT

DATED: February 18, 1997

/s/ Jan Horbaly
JAN HORBALY,
Clerk

ISSUED AS A MANDATE: March 11, 1997

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

96-1066

ROBERT L. HESS,
Plaintiff-Appellant,
v.
ADVANCED CARDIOVASCULAR SYSTEMS, INC.,
Defendant-Appellee.

ADVANCED CARDIOVASCULAR SYSTEMS, INC.,
Plaintiff/Cross-Complainant Defendant-Appellee,
v.
SCIMED LIFE SYSTEMS, INC.,
Defendant,
and
ROBERT L. HESS,
Cross-Complainant/Appellant.

Keith V. Rockey, Dressler, Rockey, Milnamow & Katz, Ltd., of Chicago, Illinois, argued for plaintiff-appellant and cross-complainant/appellant. With him on the brief was *Kathleen A. Lyons*.

Craig B. Bailey, Fulwider Patton Lee & Utecht, of Los Angeles, California, argued for defendant-appellee and plaintiff/cross-complainant defendant-appellee. With him on the brief were *Richard A. Bardin* and *Paul M. Stull*. Of counsel on the brief was *Mark B. Mondry*, Advanced Cardiovascular Systems, Inc., of Santa Clara, California.

Appealed: U.S. District Court for the Northern District of California

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

96-1066

ROBERT L. HESS,
Plaintiff-Appellant,
v.
ADVANCED CARDIOVASCULAR SYSTEMS, INC.,
Defendant-Appellee.

ADVANCED CARDIOVASCULAR SYSTEMS, INC.,
Plaintiff/Cross-Complainant Defendant-Appellee,
v.
SCIMED LIFE SYSTEMS, INC.,
Defendant,
and
ROBERT L. HESS,
Cross-Complainant/Appellant.

DECIDED: February 18, 1997

Before NEWMAN, *Circuit Judge*, FRIEDMAN, *Senior Circuit Judge*, and MICHEL, *Circuit Judge*.

FRIEDMAN, *Senior Circuit Judge*.

This appeal challenges the decision of the United States District Court for the Northern District of California that the materials and suggestions the appellant Robert L. Hess provided to the listed inventors of a patent did not make him a co-inventor of the patented device. We affirm.

I.

A. United States Patent No. 4,323,071 (the '071 patent), which listed Drs. John B. Simpson and Edward W. Robert as the inventors, covers a balloon angioplasty catheter that is inserted into a patient's artery which has a partial blockage, or stenosis. The balloon, fitted to the catheter, is inflated by forcing a radiographic fluid into it under pressure; the resulting expansion of the balloon eliminates or reduces the blockage of the artery.

While developing the catheter, Drs. Simpson and Robert were postdoctoral Cardiology Fellows at Stanford University Medical Center. A Swiss physician, Dr. Gruntzig, had pioneered the development of balloon angioplasty. After hearing Dr. Gruntzig speak at a cardiology conference at Stanford in March 1977 and later meeting him, Dr. Simpson spent time with Dr. Gruntzig in Europe, observing him perform balloon angioplasty procedures.

Upon returning to the United States Dr. Simpson discovered that Gruntzig catheters, made only in Switzerland, were in short supply. Drs. Simpson and Robert then decided to construct their own catheter. They had not examined the Gruntzig catheter in detail, but knew it had a balloon mounted on a shaft.

In attempting to find a material from which a balloon could be made, the doctors first experimented with a plastic called polyvinylchloride, which was ineffective, and next tried Teflon tubing, which produced unsatisfactory balloons. One of their Stanford colleagues (Bill Sanders) then referred them to the appellant Mr. Hess, an engineer at Raychem Corporation. At that time Mr. Hess was a technical liaison between Raychem's domestic and foreign operations; prior to that he had headed a business development group. Sanders made the suggestion because Raychem was one of the largest manufacturers of heat shrinkable materials and "might have some material" with which they could work.

The doctors told Mr. Hess, who had no previous experience with angioplasty, about the Gruntzig catheter. They stated they "wanted to . . . build a catheter . . . that incorporated a balloon on the end of a shaft." They explained what they were attempting to do, the problems they had encountered in finding a suitable material for the balloon, and that they were looking for a new material. They stated that the materials they had tried did not enable them properly to control balloon expansion.

Mr. Hess suggested that the doctors try Raychem's heat shrinkable irradiated modified polyolefin tubing and demonstrated how such a material could be used to form a balloon by heating the tubing above its crystalline melting point, applying pressure, and then cooling the material. Mr. Hess also suggested the use of an adhesive-free seal to attach the balloon to the catheter. He described how one end of the tubing could be shrunk fit onto the central shaft of the catheter without the use of any potentially-toxic adhesive chemicals. Mr. Hess stated that "the basic principles which I taught them"—involving heating the tubing "above its crystalline melting point, expanding it while it remains heated using internal pressure and then cooling it in its expanded state while your [sic] maintaining the pressure"—were "in various published textbooks and the like" and "was a generally known process to a number of companies."

Mr. Hess provided "multiple samples of . . . tubing," with which the doctors "experimented." At that meeting and in further discussions with the doctors, Mr. Hess also suggested "approaches to construction of the catheter" using the Raychem tubing.

Using that tubing, Drs. Simpson and Robert then developed and built their catheter. They had "difficulty . . . developing the . . . catheter" and spent "hours and days trying to configure this system to make it work," including "experimentation . . . with the tubing" Mr. Hess "gave" them. The two doctors worked on the

catheter "virtually every day [for] four or five hours or more." The doctors finally developed the balloon using a technique called free-blowing, a technique which Mr. Hess admittedly did not suggest. Pursuant to Mr. Hess's suggestion, the doctors attempted to avoid the use of adhesives and shrink fit the balloon to the catheter shaft, but they encountered leakage problems. Without Mr. Hess's assistance and after further experimentation, the doctors ultimately developed an acceptable adhesive-free seal. Mr. Hess did not participate in the day-to-day experimentation.

The doctors applied for a patent on their catheter in April, 1978 and the '071 patent issued with twenty-one claims (the "original claims") in April, 1982. The two inventors organized the appellee company Advanced Cardiovascular Systems, Inc. (ACS), to which they assigned the '071 patent, and began manufacturing and selling the catheter. An ACS officer stated that the "catheter gained widespread success in the marketplace, and sales of the product grew rapidly," and that the Simpson-Robert catheter "was profitable" to ACS. Raychem supplied ACS with tubing for manufacturing the catheters.

B. In 1987, ACS sued SciMed Life Systems, Inc. (SciMed) in the United States District Court for the District of Minnesota for infringement of the '071 patent. The district court granted SciMed's motion for summary judgment of non-infringement, based on its interpretation of the claims. This court, however, vacated and remanded, rejecting the district court's claim interpretation. *Advanced Cardiovascular Sys., Inc.* v. *SciMed Life Sys., Inc.*, 887 F.2d 1070, 12 USPQ2d 1539 (Fed. Cir. 1989).

The question of Mr. Hess's alleged co-inventorship apparently first arose when in its answer SciMed asserted, as one ground for challenging the validity of the patent, that there was a "failure of the patentees to join Hess as a co-patentee." In a declaration Mr. Hess executed in 1988, which SciMed filed in the patent infringement case, he described the aid he had given to

Drs. Simpson and Robert in connection with the development of their catheter. In a 1990 affidavit, he repeated those statements and asserted that he "made substantive contributions to the subject matter disclosed" in the '071 patent and "should be named as a co-inventor thereof."

In September, 1987, ACS requested reexamination of certain claims in the '071 patent. In May 1990, the Patent and Trademark Office issued a reexamination certificate, which upheld the original claims and added claims 22-52 (the "reexamination claims").

In the summer of 1990, Mr. Hess intervened in the ACS-SciMed suit to file a cross-complaint against ACS seeking a declaration that he was a joint inventor of the catheter the '071 patent covered and seeking correction of the patent to reflect his status. The district court dismissed Mr. Hess's cross-complaint for failing to state a claim on which relief could be granted because the complaint was barred by laches. This court vacated the dismissal and remanded, holding that there were disputed issues of material fact with respect to laches that precluded dismissal. *Advanced Cardiovascular Sys., Inc. v. SciMed Life Sys., Inc.*, 988 F.2d 1157, 26 USPQ2d 1038 (Fed. Cir. 1993).

While that appeal was pending, Mr. Hess filed suit in United States District Court for the Northern District of California against ACS, alleging that he was a co-inventor of the catheter the reexamination claims covered.

On the eve of trial ACS and SciMed settled their infringement suit. The Minnesota District Court then transferred to the Northern District of California Court the remaining portion of the case, which was Mr. Hess's cross-complaint asserting his co-inventorship of the catheter the '071 patent covers. The California District Court consolidated the two cases.

The California District Court granted summary judgment that Mr. Hess's claim of co-inventorship of the catheter the original claims covered was barred by laches, and set for trial the co-ownership issue with respect to the reexamination claims.

After a bench trial, the district court held that the evidence did not establish Mr. Hess's claim of co-inventorship of the catheter the reexamination claims covered. Ruling from the bench, the court determined that Mr. Hess was required to prove co-inventorship by clear and convincing evidence. The court stated:

> [A]ll that Mr. Hess needs to establish is that he conceived some important element or some important claim that is claimed in the patent . . . .
>
> . . . .
>
> . . . I don't think it's necessary for Mr. Hess to conceive of every feature of the catheter, but that he have some conceptual role in at least an important or a necessary element, or important and necessary claim.

The court noted:

> [I]nventors can obtain the services and ideas and product of others without losing their exclusive right to ownership . . . .
>
> . . . .
>
> So merely that Mr. Hess was consulted, Mr. Hess made some contribution, doesn't in and of itself rise to the level of conception particularly if he's doing nothing more than explaining to the inventors what the then state of the art was and supplying a product to them for use in their invention.

The court found that

> the information provided by Mr. Hess really didn't rise to the level of conception; that most, if not all, of his discussion with them were [sic] telling them what was available in the marketplace by way of product, and telling them how the product worked, and they, that is, Simpson and Robert, were the ones who used the product or used the—yes, used the product provided in their work.
>
> . . . .
>
> [W]hen they were meeting with Mr. Hess, I think what Mr. Hess was doing was showing them available product, telling them its properties, telling them how it could be used, and how it might be used.
>
> . . . Raychem became a supplier of product to Simpson and Robert, really all of which really leaves [sic] me to the conclusion that Mr. Hess' role was really as a representative of Raychem who is making available to a customer or potential customer the product that Raychem has, and its property uses and adaptation to what the inventors here wanted to do.
>
> . . . .
>
> [I]t's [sic] also clear from the record that Mr. Hess didn't know anything about angioplasty or medical catheters until discussion with Dr. Robert and Dr. Simpson.

Finally, the court stated:

> I do wish to state for the record that on a factual basis after having heard the evidence in the case, I'm also concluding that the evidence did not establish coinventorship of the original claims in the '071 patent and not just the reissue claims for that patent.

Hess v. Advanced Cardiovascular Sys., Inc., No. C-92-1956 (N.D. Cal. Feb. 3, 1995).

II.

The patent laws provide that whoever "invents" patentable subject matter is entitled to a patent thereon, 35 U.S.C. § 101 (1994), and that when an "invention" is "made by two or more persons jointly, they shall apply for [a] patent jointly." 35 U.S.C. § 116 (1994). The statute also deals with the situation where an inventor is not named in the application or the issued patent. 35 U.S.C. §§ 116, 256 (1994). Section 256 provides that if "through [inadvertent] error an inventor is not named in an issued patent...the Commissioner [of Patents] may...issue a certificate correcting such error," and that "[t]he court...may order correction of the patent...and the Commissioner shall issue a certificate accordingly."

The district court held that Mr. Hess had to prove his claim of co-inventorship by clear and convincing evidence, and that Mr. Hess had not done so. Mr. Hess challenges both of these rulings.

A. As the Court of Claims (whose decisions bind us, *South Corp. v. United States*, 690 F.2d 1368, 1370, 215 USPQ 657, 658 (Fed. Cir. 1982) (in banc)) stated in *Garrett Corp. v. United States*, 422 F.2d 874, 880, 164 USPQ 521, 526 (Ct. Cl.), *cert. denied*, 400 U.S. 951 (1970), "[t]he burden of showing misjoinder or nonjoinder of inventors is a heavy one and must be proved by clear and convincing evidence." Although the case involved section 116, which governs patent applications, and the present case involves section 256, which covers issued patents, the pertinent statutory language is virtually identical, and the burden of proof on this issue is the same under both sections. *See* 1 Donald S. Chisum, *Patents* § 2.03(4) at 2-31 (1996).

The rule rests on important policy considerations. "The inventors as named in an issued patent are presumed to be correct." *Amax Fly Ash Corp. v. United States*, 514 F.2d 1041, 1047, 182 USPQ 210, 215 (Ct. Cl. 1975). As the court there stated, in holding that one claiming that the inventor listed in the patent derived the invention from the claimant's work must show derivation by clear and convincing evidence, "the temptation for even honest witnesses to reconstruct, in a manner favorable to their own position, what their state of mind may have been years earlier, is simply too great to permit a lower standard." *Id.* at 1047, 182 USPQ at 215 (footnote omitted). This language is similarly applicable to claims of co-inventorship made after a patent has been issued—particularly where, as here, the patent has been outstanding for a considerable time and the patented device has been successful. In that situation, too, there is an equally strong temptation for persons who consulted with the inventor and provided him with materials and advice, to reconstruct, so as to further their own position, the extent of their contribution to the conception of the invention. In these circumstances, it would be inappropriate to permit a lower standard than clear and convincing evidence.

Mr. Hess apparently suggests that because of the particular circumstances of his participation in the activities of Drs. Simpson and Robert, the proper evidentiary standard for determining his co-inventorship claim should be preponderance rather than clear and convincing. Once the standard of proof has been determined, however—and we have held that it is clear and convincing evidence for determining co-inventorship—it applies without regard to the circumstances of a particular case. Permitting the exception Mr. Hess urges could significantly undermine the designated standard of proof, since litigants always can assert, and sometimes effectively, that their cases involve special circumstances.

B. Mr. Hess concedes that the district court "articulat[ed] the appropriate test for inventorship." The district court's standard was whether Mr. Hess "conceived some important element or some important claim that is claimed in the patent," and whether he had "some conceptual role in at least an important or a necessary element, or important and necessary claim." Mr. Hess argues, however, that the court "completely misapplied" that standard "in finding that Hess's contributions were not inventive." This argument, however, is in reality only a reformulation of the contention that the district court's findings upon which the court based its conclusion that Mr. Hess had not established co-inventorship, are clearly erroneous.

We have carefully reviewed the evidence in the record. Although there is some conflict on the question of co-inventorship, the district court's findings that Mr. Hess was not a co-inventor of the catheter claimed in the '071 patent are not clearly erroneous.

When Drs. Simpson and Robert first met with Mr. Hess, he was totally unfamiliar with angioplasty catheterization and the problems it involved. They explained to him what they were trying to do, and what difficulties they encountered. He recommended a Raychem product that he believed would be suitable for making a balloon, showed them how a balloon could be formed by heating both ends of the tube (a procedure they did not use in making their patented catheter, and made other suggestions for making the catheter, using the Raychem tubing. Although the doctors followed and utilized some of Mr. Hess's suggestions in their extensive further research, testing and construction of their catheter, the district court justifiably concluded on this record that it was they, and not Mr. Hess, who actually conceived and made the patented invention and that Mr. Hess's contributions to the inventions did not constitute the conception necessary to establish co-inventorship.

More than 140 years ago the Supreme Court, in holding that Samuel Morse's discussions with scientists in connection with his invention of the telegraph did not alter his status of the sole inventor of that device, stated:

> No invention can possibly be made, consisting of a combination of different elements ... without a thorough knowledge of the properties of each of them, and the mode in which they operate on each other. And it can make no difference, in this respect, whether [the inventor] derives his information from books, or from conversation with men skilled in the science. If it were otherwise, no patent, in which a combination of different elements is used, could ever be obtained.

O'Reilly v. Morse, 56 U.S. 62, 111 (1853).

Similarly, in *Shatterproof Glass*, this court stated that

> [a]n inventor "may use the services, ideas, and aid of others in the process of perfecting his invention without losing his right to a patent."

Shatterproof Glass Corp. v. *Libbey-Owens Ford Co.*, 758 F.2d 613, 624, 225 USPQ 634, 641 (Fed. Cir. 1985) (quoting *Hobbs* v. *United States Atomic Energy Comm'n*, 451 F.2d 849, 864, 171 USPQ 713, 724 (5th Cir. 1971)).

Mr. Hess relies on the following statement in the 1914 district court opinion in *DeLaski & Thropp Circular Woven Tire Co.*v. *William R. Thropp & Sons Co.*, 218 F. 458, 464 (D.N.J., 1914), *aff'd*, 226 F. 941 (3d Cir. 1915), which he describes as "the controlling legal standard."

> The conception of the entire device may be due to one, but if the other makes suggestions of practical value, which assisted in working out the main idea and making it operative, or contributes an independent part of the

> entire invention, which is united with the parts produced by the other and creates the whole, he is a joint inventor, even though his contribution be of comparatively minor importance and merely the application of an old idea.

That language, of course, is not binding precedent in this court, and its focus appears inconsistent with the approach the Supreme Court took in *Morse* and this court took in *Shatterproof Glass*. In any event, whether particular suggestions and contributions of third persons amount to co-inventorship turns on the facts of the particular case.

Here the district court found that in his consultations with Drs. Simpson and Robert, Mr. Hess was "doing nothing more than explaining to the inventors what the then state of the art was and supplying a product to them for use in their invention"; that "most, if not all, of his discussion with them were [sic] telling them what was available in the marketplace by way of product, and telling them how the product worked"; and that "what Mr. Hess was doing was showing them available product, telling them its properties, telling them how it could be used, and how it might be used." The principles Mr. Hess explained to them were well known and found in textbooks. Mr. Hess did no more than a skilled salesman would do in explaining how his employer's product could be used to meet a customer's requirements. The extensive research and development work that produced the catheter was done by Drs. Simpson and Robert. Our review of the record satisfies us that those findings are not clearly erroneous, and that they support the district court's conclusion that whatever contribution Mr. Hess made to Drs. Simpson and Robert did not constitute conception and therefore did not make Mr. Hess a co-inventor of the catheter claimed in the '071 patent.

Mr. Hess relies on snippets of the doctors' testimony in which, he asserts, the doctors conceded that Mr. Hess was

responsible for significant portions of the invention the '071 patent disclosed. Those statements, however, cannot bear the weight Mr. Hess gives them. In the context of the entire record, they do not refute the factual sufficiency of the evidence supporting the district court's decision.

III.

Mr. Hess also argues that the district court erroneously dismissed on summary judgment, as barred by laches, that portion of his case that claimed co-inventorship of the invention disclosed in the original claims. That issue, however, is moot in view of the district court's ruling that "on a factual basis after having heard the evidence in the case, I'm also concluding that the evidence did not establish coinventorship of the original claims in the '071 patent and not just the reissue claims for that patent." Accordingly, we do not consider it.

CONCLUSION

The judgment of the district court that Mr. Hess has not established his claim to co-inventorship of the catheter disclosed in the '071 patent is

AFFIRMED.

Judge Legge

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UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

ROBERT L. HESS,
Plaintiff,

vs.

ADVANCED CARDIOVASCULAR SYSTEMS, INC.,
Defendant.

ADVANCED CARDIOVASCULAR SYSTEMS, INC.,
Plaintiff,

vs.

SCIMED LIFE SYSTEMS, INC.,
Defendant.

ROBERT L. HESS,
Intervenor.

CONSOLIDATED CASE NOS.
C-92-1956 CAL; and
C-93-3438 CAL

FINAL JUDGMENT

These consolidated actions having come on for trial before this Court, Honorable Charles A. Legge presiding, and the issues having been duly tried and the Court having stated its findings of fact and conclusions of law in open court on July 26, 1995, as reflected in the Reporter's Transcript of the Proceedings thereon, it is Ordered and Adjudged as follows:

1. This Court has jurisdiction over the parties and the cause of action, and venue is not disputed.

2. Robert L. Hess ("Hess") is barred by laches from establishing any rights of inventorship or co-inventorship of the subject matter of any of the claims 1-21 of U.S. Patent No. 4,323,071 to Simpson et al. ("the '071 patent") for the reasons previously stated in open court on February 3, 1995, as reflected in the Reporter's Transcript of the proceeding on that date.

3. Hess failed to prove at trial that he is an inventor or co-inventor of added claims 22-52 of Reexamination Certificate B1 4,323,071 of the '071 patent. Therefore, Hess shall take nothing by way of these consolidated actions, and his complaint in Case No. C-92-1956 CAL and his complaint-in-intervention in Case No. C-93-3438 CAL are each hereby dismissed with prejudice.

4. The evidence would not be any different if the question of inventorship of claims 1-21 of the '071 patent had been tried, and such evidence fails to prove that Hess is an inventor or co-inventor of the subject matter of those claims.

5. ACS shall have judgment as to its counterclaims in Case Nos. C-92-1956 CAL and C-93-3438 CAL against Hess seeking declarations that Hess is not an inventor or co-inventor of the subject matter of any of claims 1-52 of the '071 patent.

6. ACS shall recover from Hess its costs herein.

7. In view of the foregoing, there being no other matter remaining to be determined and there being no just reason for delay, these judgments shall be deemed final.

(September 1 sn)

Dated: August __, 1995

/s/ Charles A. Legge
HONORABLE CHARLES A. LEGGE
United States District Court Judge

Prepared by:

FULWIDER PATTON LEE & UTECHT

By: /s/ Paul M. Stull
Paul M. Stull
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ADVANCED CARDIOVASCULAR
SYSTEMS, INC.

Approved as to form:

ROCKEY, RIFKIN AND RYTHER

By: /s/ Keith V. Rockey
Attorneys for Plaintiff,
ROBERT L. HESS

IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA BEFORE THE HONORABLE CHARLES A. LEGGE, JUDGE

ROBERT HESS,
Plaintiff,
vs.
ADVANCED CARDIOVASCULAR SYSTEMS,
Defendant.

No. C-92-1956 CAL

WEDNESDAY, JULY 26, 1995

SAN FRANCISCO, CALIFORNIA

ADVANCED CARDIOVASCULAR SYSTEMS, INC.,
Plaintiff,
vs.
SCIMED LIFE SYSTEMS,
Defendant.

No. C-93-3438 CAL

REPORTER'S TRANSCRIPT OF PROCEEDINGS

APPEARANCES:

For Plaintiff Hess:
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Reported By:
DIANE E. SKILLMAN,
Official Court Reporter, USDC

For Defendant Advanced Cardiovascular Systems:
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URGE THE COURT TO DO SO.

AND I THINK THAT CONCLUDES MY REMARKS.

THE COURT: OKAY. DOES THE MATTER STAND SUBMITTED?

ALL RIGHT. I'M GOING TO STATE MY DECISIONS HERE FOR THE RECORD RIGHT HERE IN OPEN COURT THIS AFTERNOON. I DON'T THINK THERE IS ANY NECESSITY FOR ME TAKING THE MATTER UNDER ANY LENGTHY SUBMISSION.

THE TRIAL HAS BEEN QUITE RECENT AND YOUR BRIEFS HAVE BEEN COMPLETED. AND AS I WILL STATE, I DON'T THINK REALLY THE MATTERS AT ISSUE ARE REALLY ALL THAT COMPLICATED AND I DON'T THINK THAT FURTHER WORK ON MY PART IN THE CLOISTER CONTEMPLATION OF CHAMBERS WOULD REALLY DO ANY GOOD AT ALL.

SO I THINK I AM AS FULLY PREPARED TO RESOLVE THE MATTER TODAY AS I COULD BE ON FURTHER STUDY. I HAVE REVIEWED THE RECORDS, THE TRIAL, AS WELL AS THE MATERIAL YOU SUBMITTED TO ME POST TRIAL.

NOW, FIRST OF ALL, JURISDICTION HERE IS PROPER HERE UNDER 35 U.S.C. SECTION 256 AND 28 U.S.C. SECTION 1338. I DON'T BELIEVE THERE IS ANY DISPUTE OF JURISDICTION. NOR DO I BELIEVE THAT THERE IS ANY DISPUTE REGARDING THE VENUE BEING PROPER HERE UNDER THE APPROPRIATE STATUTE, WHICH I BELIEVE IS 1391.

WE'RE DEALING WITH TWO CASES HERE. THE MAIN ONE BEING 92-1956, BUT WE ALSO HAVE

93-3438. I BELIEVE THAT THE CASES, AT LEAST INSOFAR AS THEY INVOLVE MR. HESS ON ONE SIDE

AND THE DEFENDANT OR DEFENDANTS ACS ON THE OTHER SIDE HAVE BEEN CONSOLIDATED, OR AT LEAST CONSOLIDATED FOR TRIAL.

THE TRIAL HAS BEEN CONDUCTED. IT HAS BEEN A NONJURY TRIAL. I'M NOT SURE WHETHER THE PARTIES ENDED UP STIPULATING TO NONJURY TRIAL OR NOT, BUT EVEN IF THEY DID NOT, I BELIEVE THE PRINCIPAL RELIEF HERE IS EQUITABLE RELIEF, AND IN ADDITION, THE RECENT DECISION OF THE UNITED STATES SUPREME COURT DETERMINING THAT THE APPROPRIATE DECIDER OF FACTS FOR PATENT MATTERS INVOLVING CLAIM INTERPRETATION IS THE COURT AND NOT A JURY. AND IN ORDER TO DECIDE INVENTORSHIP, I THINK IT IS, HAS BEEN, AND WILL BE NECESSARY FOR ME TO INTERPRET CLAIMS OF BOTH THE PATENT AND THE REISSUE CERTIFICATE.

NOW AS I'VE SAID, JUST TO REPEAT A COUPLE OF MATTERS SO THE RECORD IS COMPLETE. I'VE READ THE TESTIMONY OF THE WITNESSES. I'VE READ ALL OF THE EXHIBITS. I'VE READ THE POST TRIAL MATERIAL YOU SUBMITTED TO ME, INCLUDING THE ADDITIONAL PORTIONS OF THE DEPOSITION OF MR. HESS. AND I'VE, AS I SAID, READ YOUR BRIEFS AND READ THE LAW FROM THE BRIEFS AND READ THE CASES AND STATUTES AS I BELIEVE NECESSARY.

SO MY STATEMENTS HERE ON THE RECORD WILL CONSTITUTE THE FINDINGS OF FACT AND

CONCLUSIONS OF LAW THAT I AM MAKING IN CONNECTION WITH THE CASE AND WILL BE AN ORDER FOR THE ENTRY OF THE JUDGMENT.

NOW, THE PRINCIPAL ISSUE WE'RE CONFRONTED WITH HERE IS WHETHER MR. HESS IS AN INVENTOR OR COINVENTOR OF SOME OR

ALL OF THE CLAIMS IN THE OS — IN THE '071 PATENT AND IN THE REEXAMINATION CERTIFICATE UNDER THE '071 PATENT.

THE STATUTORY BASIS FOR THAT KIND OF A CLAIM IS SET FORTH IN TITLE 35 SECTION 256. SO THE ISSUE, AT LEAST IN ITS DEFINITION, IS A VERY NARROW ONE, AND THAT IS, DID — WAS MR. HESS AN INVENTOR OR COINVENTOR WITH RESPECT TO SOME OR ALL OF THE CLAIMS. THAT IS THE ISSUE, THE CENTRAL ISSUE.

I THINK THAT ALL OF THE OTHER ISSUES IN THE CASE ARE EITHER MADE MOOT BY IT OR FLOW FROM IT, INCLUDING CLAIMS THAT I HAVE SEVERED AND STAYED FOR FURTHER CONSIDERATION.

NOW, FIRST OF ALL, I BELIEVE IT'S APPROPRIATE TO DEFINE THE LEGAL STANDARDS UNDER WHICH I'M VIEWING THE EVIDENCE AND MAKING THE DECISIONS.

FIRST OF ALL, THERE IS A PRESUMPTION THAT THE INVENTORS NAMED IN THE ISSUED PATENT ARE CORRECT. I DON'T BELIEVE I NEED TO, REALLY NEED TO CITE ANY CASE LAW OR STATUTORY LAW FOR THAT PROPOSITION, AND IT HAS BEEN

REPEATED MANY TIMES, SO I WILL NOT ADD ANY CASE CITATIONS HERE.

WHAT IS THE LEGAL STANDARD FOR WHEN SOMEBODY IS OR IS NOT AN INVENTOR? I THINK YOU BOTH AGREE THAT THE BASIC ONE, THE ESSENTIAL STEP IS CONCEPTION, AND I THINK YOU BOTH USE THE DEFINITION IN *SEWALL VERSUS WALTERS*, A RECENT DECISION OF THE FEDERAL CIRCUIT AS THE BASIS FOR THAT DEFINITION. I ALSO PICKED UP ON THE SAME THING IN THE *IDACON* CASE IN THE DISTRICT COURT OF OKLAHOMA WITH AN EARLIER DATE.

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NOW THE QUESTION, AT LEAST I THOUGHT IT WAS A QUESTION, WHEN — FROM THE BRIEFING, IS TO WHAT MR. HESS NEEDS TO HAVE CONCEPTUALIZED IN ORDER TO BE AN INVENTOR.

IT WAS MY UNDERSTANDING OF DEFENDANT'S POSITION THAT HE COULD NOT BE A COINVENTOR UNLESS HE HAD, SHALL WE SAY QUOTE "CONCEIVED" OF THE COMPLETED CATHETER ASSEMBLY, INCLUDING EVERY INDIVIDUAL FEATURE OF IT.

I'M NOT SURE THAT THAT'S THE POSITION THAT WAS JUST ARTICULATED A FEW MINUTES AGO BY MR. BAILEY, BUT IN ANY EVENT, I THINK THAT ALL THAT MR. HESS NEEDS TO ESTABLISH IS THAT HE CONCEIVED SOME IMPORTANT ELEMENT OR SOME IMPORTANT CLAIM THAT IS CLAIMED IN THE PATENT, AND NEED NOT HAVE SAT DOWN AND SAYS HERE IS WHAT THE WHOLE DEVICE IS GOING TO LOOK LIKE WHEN WE'RE FINISHED.

I THINK THAT CONCLUSION, THAT IS, THAT THE PLAINTIFF'S BURDEN IS WITH RESPECT TO SOME IMPORTANT ELEMENT OR SOME IMPORTANT CLAIM IS REALLY WHAT IS CONTEMPLATED IN THE ENTIRE DEFINITION OF THE JOINT OWNERSHIP CONCEPT IN THE STATUTE 35 U.S.C. SECTION 116, AND IN THE EARLIER *MONSANTO VERSUS KAMP* DECISION, WHICH I THINK IS PROBABLY PICKED UP BY CONGRESS AND MADE INTO THAT SECTION 116.

SO, I DON'T THINK IT'S NECESSARY FOR MR. HESS TO CONCEIVE OF EVERY FEATURE OF THE CATHETER, BUT THAT HE HAVE SOME CONCEPTUAL ROLE IN AT LEAST AN IMPORTANT OR A NECESSARY ELEMENT, OR IMPORTANT AND NECESSARY CLAIM.

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NOW, THAT HAVING BEEN SAID, IT IS NOT, OF COURSE, EVERY COMMUNICATION BY THESE NAMED INVENTORS WITH MR. HESS THAT WILL LEAD TO A CO-OWNERSHIP CONCLUSION. I THINK IT'S QUITE CLEAR THAT INVENTORS CAN OBTAIN THE SERVICES AND IDEAS AND PRODUCTS OF OTHERS WITHOUT LOSING THEIR EXCLUSIVE RIGHT TO OWNERSHIP, AND IN THAT CONTEXT, WE GET BACK TO THE BASIC IDEA OF A CONCEPTION OF AN IMPORTANT ELEMENT OF THE CLAIMS.

I THINK IT'S ALSO TRUE THAT IN THIS CONSULTING WITH OTHERS, BEING TAUGHT THE CURRENT STATE OF THE ART ON SOMETHING OR THE SUPPLYING OF A PARTICULAR PRODUCT FOR USE IS NOT NECESSARILY CONCEPTION. I THINK THAT'S BEEN MADE CLEAR AGAIN RECENTLY BY THE

SEWALL DECISION OF THE FEDERAL CIRCUIT AND EARLIER BY THIS *IDACON* CASE OF THE OKLAHOMA DISTRICT, WHICH I QUOTED EARLIER.

SO MERELY THAT MR. HESS WAS CONSULTED, MR. HESS MADE SOME CONTRIBUTION, DOESN'T IN AND OF ITSELF RISE TO THE LEVEL OF CONCEPTION PARTICULARLY IF HE'S DOING NOTHING MORE THAN EXPLAINING TO THE INVENTORS WHAT THE THEN STATE OF THE ART WAS AND SUPPLYING A PRODUCT TO THEM FOR USE IN THEIR INVENTION.

WE ALSO HAVE A SUBSPAN ON THE APPROPRIATE STANDARD WHERE WE'RE DEALING WITH DEPENDENT CLAIMS AS WE ARE IN THE REISSUE CERTIFICATE. AND THAT IS THAT CERTAIN FEATURES RECITED IN THE DEPENDENT CLAIMS ARE NOT NECESSARILY INVENTIVE FEATURES OVER AND ABOVE THE INDEPENDENT CLAIMS THEMSELVES.

SO, THAT HAVING BEEN SAID, THOSE I BELIEVE ARE THE

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LEGAL STANDARDS AND THE LEGAL PRINCIPLES TO BE APPLIED — TO WHICH THE EVIDENCE HAS TO BE APPLIED.

NOW WHAT ABOUT THIS BURDEN OF PROOF? THERE IS NO DOUBT THAT THE BURDEN OF PROOF IS ON MR. HESS. AND THE QUESTION ARISES WHETHER IT IS A PREPONDERANCE OF THE EVIDENCE STANDARD OR A CLEAR AND CONVINCING STANDARD. I THINK THAT THE STANDARD IS A CLEAR AND CONVINCING STANDARD.

CERTAINLY SEVERAL CASES HAVE SAID THAT. MR. HESS' COUNSEL CALLS THAT INTO DOUBT BY CITATION TO THE *AMERICAN HOIST* DECISION. HOWEVER, EVEN AFTER THAT CITATION OF *AMERICAN HOIST*, *AMERICAN HOIST* ITSELF GOES ON TO STATE AS FOLLOWS.

> I QUOTE: "INDEED NEW PRIOR ART NOT BEFORE THE PTO MAY SO CLEARLY INVALIDATE A PATENT, BUT THE BURDEN IS FULLY SUSTAINED MERELY BY PROVING ITS EXISTENCE AND APPLYING THE PROPER LAW: BUT THAT HAS NO EFFECT ON THE PRESUMPTION OR ON WHO HAS THE BURDEN OF PROOF. NEITHER DOES THE STANDARD OF PROOF CHANGE; IT MUST BE BY CLEAR AND CONVINCING EVIDENCE OR ITS EQUIVALENT BY WAY OF A FORM OF WORDS IT MAY BE EXPRESSED." END OF QUOTE.

NOW I DON'T THINK THAT IS LIMITED TO A PRIOR ART CASE. I THINK THE SAME THING APPLIES TO AN INVENTORSHIP CASE. SO I BELIEVE THAT THE APPROPRIATE STANDARD IS ONE OF CLEAR AND CONVINCING EVIDENCE. AND WHERE I STATE FACTS HERE, THEY ARE STATED TO BE

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FACTS WHERE APPROPRIATE BY THIS CLEAR AND CONVINCING STANDARD.

NOW CERTAIN OF THE FACTS IN THE CASE ARE UNCONTESTED, AND WITHOUT REPEATING THOSE, I'LL SIMPLY INCORPORATE BY REFERENCE THE STATEMENT OF UNDISPUTED FACTS THAT IS SET FORTH IN THE JOINT PRETRIAL STATEMENT ON PAGES 8 THROUGH 10.

NOW AS TO THE FACTS IN CONTEST, EVEN AFTER ALL OF THIS WORK DONE BY COUNSEL ON BOTH SIDES, TESTIMONY BY THE WITNESSES, AND THE VOLUMES OF PAPER WE HAVE HERE, THERE DOESN'T REALLY SEEM TO BE MUCH OR MANY TRUE CONFLICTS IN THE EVIDENCE IN THE SENSE OF WHICH THE COURT NORMALLY DEALS WITH.

IN FACT, I FIND VERY FEW CONFLICTS ON THE KEY POINTS IN THIS CASE, AND THAT IS, WHAT DID MR. HESS DO WITH RESPECT TO THIS INVENTION.

MOSTLY THE ISSUE COMES DOWN TO CONCLUSIONS OF FACT OR CONCLUSIONS OF LAW TO BE DRAWN FROM THE FACTS THAT THE WITNESSES WERE REALLY NOT DEBATING ABOUT.

I BELIEVE REALLY THE ONLY MATERIAL TRUE CONFLICT IN THE TESTIMONY WAS THE CONFLICT BETWEEN DR. SIMPSON AND DR. ROBERT ON THE ONE HAND AND DR. HESS ON THE OTHER AS TO WHO FIRST CAME UP WITH THE COAXIAL IDEAS.

ALL RIGHT. THEN APPLYING WHAT THE EVIDENCE IS TO THE . . . WITH THAT BURDEN OF PROOF AND TO THE STANDARD OF LAW, I HAVE TO FIRST REACH THE GENERAL CONCLUSION THAT MR. HESS HAS NOT BEEN ABLE TO SUSTAIN HIS BURDEN OF PROOF IN THE APPLICABLE LEGAL STANDARD.

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I DON'T BELIEVE THAT HE HAS DEMONSTRATED UNDER THE APPLICABLE BURDEN OF PROOF THE CONCEPTION AS THAT CASE — AS THAT PRINCIPLE HAS BEEN DEFINED AS TO AN IMPORTANT ELEMENT OR IMPORTANT CLAIM OF THE INVENTION.

I THINK WHAT WE HAVE IS, WITH RESPECT TO MOST OF IT IS WHERE IN DEED DR. ROBERTS — DR. ROBERT, DR. SIMPSON DID GO TO MR. HESS, DID GO TO RAYCHEM, BUT THAT THE INFORMATION PROVIDED BY MR. HESS REALLY DIDN'T RISE TO THE LEVEL OF CONCEPTION; THAT MOST, IF NOT ALL, OF HIS DISCUSSION WITH THEM WERE TELLING THEM WHAT WAS AVAILABLE, IN THE MARKETPLACE BY WAY OF PRODUCT, AND TELLING THEM HOW THE PRODUCT WORKED, AND THEY, THAT IS, SIMPSON AND ROBERT, WERE THE ONES WHO USED THE PRODUCT OR USED THE — YES, USED THE PRODUCT PROVIDED IN THEIR WORK.

I THINK THAT PRINCIPLE ALSO APPLIES TO THE CONCEPT OF TEACHING THE PRIOR ART AND THE — I'M REPEATING MYSELF, I GUESS, MAKING ALREADY AVAILABLE PRODUCT AVAILABLE TO THE INVENTORS.

NOW, IN ALL OF THIS, I DO NOT MEAN TO DEMEAN IN ANY WAY MR. HESS' INTEGRITY OR HIS INTELLIGENCE OR HIS OWN INGENUITY OR HIS COMPETENCE AS A WITNESS OR HIS HONESTY AS A WITNESS.

I THINK THE FACTS WERE THE FACTS, AND I THINK THEY WERE VERY CLEARLY SET FORTH AND MR. HESS CERTAINLY HAD A ROLE IN THIS.

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I THINK THAT ROLE IS PROBABLY DEFINED AS WELL AS ANYBODY COULD DEFINE IT IN EXHIBIT 31, WHICH I BELIEVE IS THE NUMBER OF THE LETTER FROM DR. SIMPSON TO RAYCHEM WHICH CERTAINLY COMPLIMENTS MR. HESS.

THAT LETTER IS PERHAPS A BIT OF EMBARRASSMENT TO THE DEFENDANTS IN THE CONTEXT OF THIS CASE, BUT IT DOES STATE TO A DEGREE OF ACCURACY MR. HESS' PARTICIPATION AND I THINK IT'S BLOWING ALL THE SMOKE AT RAYCHEM FOR THE GENERAL IDEA OF INVOLVING RAYCHEM IN FUTURE DEVELOPMENTS, IT'S OVERSTATING THE CASE, BUT NEVERTHELESS IT IS CLEARLY SOME DEBT OF GRATITUDE AT LEAST BY SIMPSON AND ROBERT TO MR. HESS, ALBEIT I'M FINDING THAT THAT IS NOT A DEBT THAT RISES TO A LEVEL OF BEING A COINVENTOR.

I WANT TO MAKE A FEW COMMENTS BY WAY OF FACTUAL FINDINGS OR JUST COMMENTING ON THE EVIDENCE WITH RESPECT TO A FEW THINGS.

FIRST OF ALL, THE THREE ELEMENTS WHICH MR. ROCKEY HAS ARGUED REALLY AREN'T IN DISPUTE. THAT IS THE FEATURES, LET'S CALL IT, THAT MR. HESS CONSULTED WITH DR. SIMPSON AND DR. ROBERT ABOUT. AND THAT IS THE MATTER DEALING WITH THE MATERIALS, THE SHAPING OF IT INTO THE BALLOON, AND THE HEAT-SHRINK PROPERTY AND USES OF HEAT-SHRINK TUBING INCLUDING THE ABILITY TO SEAL A TUBING AROUND THE ROD WITHOUT THE USE OF AN ADHESIVE.

NOW IT SEEMS TO ME WHAT THIS SITUATION REALLY JUST

IS NOT INVENTORSHIP. IT MAY HAVE A CERTAIN DEGREE OF INGENIOUSNESS TO IT, BUT THAT IS NOT INVENTORSHIP. THAT IS, RAYCHEM HAD THIS PRODUCT. HEAT-SHRINK TUBING WAS ON THE

MARKET. IT MAY NOT BE KNOWN TO SIMPSON AND ROBERT, BUT IT WAS A PRODUCT RAYCHEM HAD BEEN MAKING, AND SOMEBODY KNEW ABOUT IT. THEY WERE REFERRED SPECIFICALLY TO, I THINK — THERE IS A SMALL CONFUSION IN THE EVIDENCE HERE AS TO EITHER SPECIFICALLY MR. HESS OR RAYCHEM GENERALLY, TO SEE IF HEAT-SHRINK TUBING COULDN'T DO THE JOB.

SO WHEN THEY WERE MEETING WITH MR. HESS, I THINK WHAT MR. HESS WAS DOING WAS SHOWING THEM AVAILABLE PRODUCT, TELLING THEM ITS PROPERTIES, TELLING THEM HOW IT COULD BE USED, AND HOW IT MIGHT BE USED. SO I REALLY DON'T THINK — WELL, IN ADDITION, I THINK IT IS SIGNIFICANT THAT THE PATENT ITSELF DISCLOSES THE RAYCHEM MATERIAL AS BEING PART OF THE PRIOR ART IN THE CASE.

AND IN ADDITION, THERE WERE LATER MEETINGS BETWEEN SIMPSON AND ROBERT ON THE ONE HAND AND RAYCHEM PEOPLE ON THE OTHER OBVIOUSLY LEADING TO THE RELATIONSHIP WHERE RAYCHEM BECAME A SUPPLIER OF PRODUCT TO SIMPSON AND ROBERT, REALLY ALL OF WHICH REALLY LEAVES ME TO THE CONCLUSION THAT MR. HESS' ROLE WAS REALLY AS A REPRESENTATIVE OF RAYCHEM WHO IS MAKING AVAILABLE TO A CUSTOMER OR POTENTIAL, CUSTOMER THE PRODUCT THAT RAYCHEM HAS, AND ITS PROPERTY USES AND ADAPTATION TO WHAT THE INVENTORS HERE WANTED TO DO. ALL OF WHICH IS IMPORTANT, BUT I

DON'T THINK RISING TO THE LEVEL OF INVENTORSHIP.

I WOULD ALSO NOTE THAT ALL THE PHYSICAL WORK ON THE DEVICE WAS DONE BY DR. SIMPSON AND DR. ROBERT, INCLUDING THE TESTING.

NOW, ONE DOESN'T HAVE TO ACTUALLY DO THE PHYSICAL WORK ON THE OBJECT IN ORDER TO BE THE INVENTOR, BUT I DO THINK IT HAS SOME EVIDENTIARY VALUE; THAT IT WAS DR. SIMPSON AND DR. ROBERT WHO REALLY WERE WORKING HARD, HARD WORKING AT THE BENCH.

I THINK IT'S ALSO CLEAR FROM THE RECORD THAT MR. HESS DIDN'T KNOW ANYTHING ABOUT ANGIOPLASTY OR MEDICAL CATHETERS UNTIL DISCUSSION WITH DR. ROBERT AND DR. SIMPSON.

ON THE QUESTION OF WHO HAD THE IDEA FOR THE COAXIAL RELATIONSHIP FOR THE CATHETER, THERE IS, AS I SAID, A CONFLICT IN THE EVIDENCE HERE AND ONE WHICH MR. HESS BEARS BY CLEAR AND CONVINCING EVIDENCE, AND I JUST DON'T THINK THE EVIDENCE CAN DO THAT.

THE TESTIMONY — REALLY THE TESTIMONY ON BOTH SIDES AS FAR AS DIRECT TESTIMONY ON THE QUESTION IS ALL VERBAL. IT'S ALL PEOPLE SAYING WHAT OCCURRED HOW MANY YEARS AGO. I REALLY FIND NO CONTEMPORANEOUS EVIDENCE IN THE FORM OF NOTES OR ANYTHING LIKE THAT TO CORROBORATE EITHER POSITION.

THE DIFFERENCES IN THE TIME LINES AS PEOPLE RECALL THEM AS MAYBE INDICATED BY WHAT

PAPER TRAIL WE DO HAVE ON THE TIME LINE IS REALLY NOT ALL THAT IMPORTANT. THE QUESTION IS

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WHO, NOT WHEN.

AND AS I BELIEVE THE DEFENSE HAS ARGUED HERE, THAT THESE EVENTS UNDER THE DEVELOPMENT OF THE CATHETER WERE IMPORTANT IN THE WORKING LIVES OF DRS. SIMPSON AND ROBERT AT THE TIME, AND INDEED — ALTHOUGH THEY WERE DOING THIS ON A PART TIME BASIS, IT WAS CERTAINLY AN OVERWHELMING ASPECT OF THEIR DAILY LIFE, WHILE MR. HESS AT THE TIME INQUIRY REALLY SEEMED TO BE MORE TANGENTIAL TO OTHER WORK HE WAS DOING FOR RAYCHEM.

BUT I THINK THIS FALTERS — MR. HESS' POSITION FALTERS ON THIS NOT FROM WHAT I BELIEVE OR DON'T BELIEVE, BUT FROM THE BURDEN OF PROOF BEING ONE OF CLEAR AND CONVINCING EVIDENCE, AND SIMPLY FACED WITH CONFLICTING TESTIMONY OF THREE WITNESSES WITH WHAT I BELIEVE TO BE NO REAL CORROBORATION OUTSIDE THAT TESTIMONY. I JUST DON'T THINK MR. HESS CAN CARRY HIS BURDEN OF NO CLEAR AND CONVINCING EVIDENCE.

I'M ALSO GIVING SOME CREDENCE AND THE WEIGHT OF THE TESTIMONY AND THE INTERPRETATION OF IT TO THE LENGTH OF TIME THAT WENT ON HERE AFTER THE DEVELOPMENT AND BEFORE MR. HESS ASSERTED HIS CLAIMS — MADE HIS CLAIMS, AND THE CONTEXT IN WHICH THEY WERE FIRST ASSERTED.

NOW, WHETHER THIS IS OR IS NOT LACHES, OR THIS IS OR IS NOT ESTOPPEL IS NOW MOOT BECAUSE OF MY DECISION THAT HE'S NOT A COINVENTOR, BUT I DO THINK THAT THE LENGTH OF TIME HAS SOME SORT OF EVIDENTIARY VALUE HERE AND I THINK IS A FACTOR IN

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WEIGHT BEING GIVEN TO SOME OF THE EVIDENCE.

SO, SINCE I AM FINDING THAT — FOR THE DEFENDANTS ON THE ISSUE — REALLY DEFENDANT ON THE ISSUE OF INVENTORSHIP WHICH IS A FACTUAL QUESTION, I AM NOT GOING TO MAKE ANY FURTHER RULING ON DEFENDANT'S AFFIRMATIVE DEFENSES SUCH AS STATUTE OF LIMITATIONS, AND LACHES, AND ESTOPPEL.

AND I ALSO THINK THAT IN VIEW OF MY CONCLUSIONS HERE WITH RESPECT TO THE HISTORY OF THE ENTIRE INVENTORSHIP, THAT EVEN INSOFAR AS THE CASE PERTAINS TO THE ORIGINAL CLAIMS AND NOT JUST THE REISSUE CLAIMS, THAT MY FINDINGS AND MY CONCLUSIONS WOULD BE ESSENTIALLY THE SAME.

I DON'T THINK THE EVIDENCE WOULD BE ANY DIFFERENT IF WE WERE RETRYING THE ORIGINAL ISSUE CASE, SO ALTHOUGH I ORIGINALLY DECIDED THE MOTION FOR PARTIAL SUMMARY JUDGMENT IN FAVOR OF DEFENDANT ON THE BASIS OF LACHES AND ESTOPPEL, I DO WISH TO STATE FOR THE RECORD THAT ON A FACTUAL BASIS AFTER HAVING HEARD THE EVIDENCE IN THE CASE, I'M ALSO CONCLUDING THAT THE EVIDENCE DID NOT ESTABLISH COINVENTORSHIP OF THE ORIGINAL

CLAIMS IN THE '071 PATENT AND NOT JUST THE REISSUE CLAIMS FOR THAT PATENT.

SO I AM DIRECTING THAT JUDGMENT BE ENTERED IN 92-1956 IN FAVOR OF DEFENDANT AND AGAINST THE PLAINTIFF ON THE SECOND AMENDED COMPLAINT AS TO COUNT 2 THAT IS BASED UPON THE FACTUAL FINDING COUPLED WITH THE APPROPRIATE LEGAL STANDARD THAT MR. HESS IS NOT A COINVENTOR.

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ON COUNT 2, THAT JUDGMENT WILL BE IN FAVOR OF DEFENDANT AND AGAINST MR. HESS BECAUSE SINCE I'M FINDING HE IS NOT A COINVENTOR, HE CERTAINLY DOES NOT HAVE A CAUSE OF ACTION FOR INTERFERENCE WITH THE ... WITH HIS BUSINESS OPPORTUNITIES AS AN ALLEGED COINVENTOR.

I AM ALSO FINDING FOR THE DEFENDANT AND AGAINST THE PLAINTIFF ON THE COUNTERCLAIMS, CERTAINLY INSOFAR AS THEY SEEK A DETERMINATION OF WHO IS THE COINVENTOR.

IN 93-3438, I HAVE FORGOTTEN FOR THE MOMENT WHAT ALL OF THE CLAIMS ARE IN THAT ACTION, BUT CERTAINLY INSOFAR AS THEY ARE AN ACTION BY ACS AGAINST MR. HESS, AND PERHAPS A COUNTERCLAIM BACK BY HIM, I THINK IT'S JUST A RECIPROCAL OF THE DECISIONS THAT I HAVE MADE IN 92-1956.

SO I WILL ASK THE DEFENDANTS TO PROVIDE PROPOSED FORMS OF JUDGMENT FOR THOSE TWO CASES. THE FORMS OF JUDGMENT SHOULD

NEEDN'T RECITE ALL THE REASONS THAT I HAVE GONE THROUGH HERE, YOU CAN SIMPLY STATE IN THERE THAT I DID STATE MY REASONS ON THE RECORD IN OPEN COURT AND THEY ARE CONTAINED IN THE REPORTER'S TRANSCRIPT, AND I DON'T THINK YOU NEED TO MAKE ANY FURTHER REPUTATION — NOT MAKE ANY FURTHER RECITATION OF THE REASONING.

OF COURSE, PLEASE SUBMIT YOUR PROPOSED FORM OF JUDGMENT TO MR. ROCKEY BEFORE YOU SUBMIT THEM TO ME.

ALL RIGHT. WELL, THANK YOU FOR YOUR EXCELLENT PRESENTATION ON BOTH SIDES OF THE CASE. I KNOW IT'S

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DISAPPOINTING TO MR. HESS AND DISAPPOINTING TO PLAINTIFFS, BUT YOU ALL KNOW THAT IS WHAT COURTS ARE HERE FOR, AND THAT IS MY NECESSITY TO MAKE A DECISION. I THINK IT WAS PRESENTED IN GOOD FAITH AND WITH GREAT COMPETENCE. I THINK YOU BOTH HAVE DONE AN EXCELLENT JOB.

I PROBABLY HAVE NOT HEARD THE END OF IT, BUT WE'LL AT LEAST GET IT OUT OF THIS COURT AND INTO ANOTHER.

THANK YOU, COUNSEL.

MR. ROCKEY: THANK YOU, YOUR HONOR.

(PROCEEDINGS ADJOURNED.)

SIMPSON — DIRECT/ROCKEY

Q. WHAT WAS THE PROBLEM?

A. WELL ... WE WOULD HAVE TO HEAT THE TEFLON TO VERY HIGH TEMPERATURES TO — SO THAT WHEN WE PRESSURIZED IT, WE WOULD TRY TO BLOW THE BALLOONS, AND WE WERE BLOWING THEM IN MOLDS, AND ... JUST WASN'T WORKING.

Q. OKAY. DID YOU EVER SUCCEED IN MAKING A BALLOON AT ALL FROM EITHER PVC OR TEFLON?

A. OH, YEAH. UH-HUH.

Q. YOU COULD MAKE ONE; YOU JUST WEREN'T SATISFIED WITH IT, I TAKE IT.

A. THAT'S RIGHT.

Q. AT THIS. ... THIS POINT WERE YOU BEGINNING TO EXPERIENCE FRUSTRATION?

A. NO, NOT AT ALL.

Q. YOU WERE NOT?

A. NO. HUH-UH.

Q. YOU HAD TRIED TWO DIFFERENT PLASTIC MATERIALS AND YOU WERE NOT SUCCESSFUL WITH EITHER ONE OF THEM.

A. THAT'S RIGHT.

Q. DID YOU CONTINUE YOUR SEARCH FOR PLASTIC MATERIALS?

A. ABSOLUTELY.

Q. AND WHAT HAPPENED WAS THAT YOU WERE — YOU KNEW A ... A GENTLEMAN ON THE STAFF AT STANFORD BY THE NAME OF BILL SANDERS, DIDN'T YOU?

A. THAT IS CORRECT.

FIT ONTO THE INNER TUBE, TO AVOID THE NECESSITY OF USING ANY ADHESIVE; CORRECT?

A. THAT'S CORRECT.

Q. IN FACT, THE PATENT DESCRIBES A TECHNIQUE BY WHICH YOU CAN HEAT THIS DISTAL END OF THE CATHETER TO EFFECT THAT SHRINK FITTING, WITHOUT TRANSMITTING ANY OF THAT HEAT TO THE BALLOON ITSELF.

CORRECT?

A. I DON'T RECALL THAT SPECIFICALLY. BUT I'M CERTAIN — YES.

Q. OKAY. AND THE IDEA FOR SHRINK FITTING THE OUTER TUBE ONTO THE INNER TUBE TO EFFECT THAT SEAL WAS A CONTRIBUTION THAT MR. HESS MADE, WASN'T IT?

A. IT IS A — A CONTRIBUTION THAT HE HELPED US WITH. THERE'S NO DOUBT ABOUT THAT, YEAH.

Q. AS A MATTER OF FACT, YOU HAD ... PROPOSED USING ADHESIVES IN THIS AREA, HAD YOU NOT?

A. I'M NOT SAYING THAT WE PROPOSED IT. WE TRIED IT. AND IT ... WAS UNSATISFACTORY.

SO WE CONTACTED MR. HESS, AND ASKED HIM FOR SOME ADVICE ON HOW TO

IMPROVE THE ADHESIVES. AND HE SAID HE WOULD JUST LEAVE THE ADHESIVES OUT.

Q. SO WOULD YOU AGREE THAT MR. HESS MADE A CONTRIBUTION TO THE CATHETER IN RESPECT TO THE USE OF SHRINK FITTING WITHOUT THE USE OF AN ADHESIVE IN THE DISTAL END?

A. YEAH, I WOULD AGREE THAT HE GAVE US SOME ADVICE ON — ON

SIMPSON — DIRECT/ROCKEY

WHAT WE COULD DO ABOUT THE ADHESIVE-RELATED PROBLEM THAT WE HAVING WERE AT THE DISTAL TIP OF THE CATHETER.

Q. WELL, DO YOU AGREE THAT THAT'S A CONTRIBUTION?

A. I DON'T KNOW HOW — I DON'T KNOW WHAT "A CONTRIBUTION" MEANS.

Q. OKAY.

NOW ... YOU HAVE NOTICED, HAVEN'T YOU, THAT SOME OF THE CLAIMS OF YOUR PATENT TALK ABOUT AN ADHESIVE-FREE SEAL AT THE DISTAL END.

A. I COULD ACTUALLY REVIEW THE PATENT, BUT I HAVE NOT REVIEWED THE PATENT IN A LONG TIME.

SO IF YOU WANT TO POINT THAT OUT TO ME —

Q. SURE.

A. — THEN I'LL BE HAPPY TO REVIEW THAT.

Q. I'D BE HAPPY TO.

LET'S TAKE — LET'S JUST TAKE A QUICK EXAMPLE OF CLAIM ... 13.

THAT'S ON THE LAST PAGE, DR. SIMPSON.

A. CLAIM 13?

Q. RIGHT.

A. UH-HUH.

(WITNESS LOOKING THROUGH DOCUMENTS.)

Q. LAST PAGE.

A. OKAY. UH-HUH.

(WITNESS READING TO HIMSELF.)

HERE THAT THE INNER MEMBER COLLAPSED AWAY FROM THE BALLOON.

SO WE HAD ANOTHER LEAKING PROBLEM AS SOON AS WE LEFT THE ADHESIVE OUT.

SO THERE'S MORE TO IT THAN JUST LEAVING THE ADHESIVE OUT TO MAKE THE THING WORK.

THE DIAMETER OF THE INNER MEMBER HAS TO BE ADJUSTED; IT HAS TO BE THICKER. SO WE HAD TO MAKE MORE CHANGES THAN JUST THAT TO KEEP THE THING FROM LEAKING.

Q. WELL, LET'S — LET'S SEE IF WE CAN TAKE THAT A STEP AT a TIME.

YOU WERE TRYING TO PUT AN ADHESIVE IN THAT AREA, WEREN'T YOU?

A. WE HAD PUT AN ADHESIVE IN THAT AREA.

Q. RIGHT.

MR. HESS SAID: NO, DON'T DO THAT.

A. THAT'S RIGHT. HE DID. ABSOLUTELY. NONDISPUTED.

Q. YOU ADOPTED HIS SUGGESTION AND YOU PUT THAT SUGGESTION IN CLAIM 13 OF YOUR PATENT, DIDN'T YOU?

A. IT SHOWS UP HERE, YES. UH-HUH.

Q. NOW, IN YOUR LETTER TO MR. COOK, WHICH IS EXHIBIT 31, WE — WE TALKED BRIEFLY ABOUT THIS ANNULAR PASSAGE (INDICATING AT EASEL) ... AND I THINK YOU KNOW THAT MR. HESS CONTENDS THAT HE MADE A SUGGESTION IN THAT DEPARTMENT; AND YOU DISPUTE IT. CORRECT?

A. THAT'S CORRECT.

SIMPSON — DIRECT/ROCKEY

BY MR. ROCKEY:

Q. AND ONE OF THE POINTS THAT YOU MADE, DR. SIMPSON, AS TO HOW THERE WAS A DIFFERENCE, WAS THAT THE '873 PATENT USED A BALLOON MADE OF A STRETCHABLE MATERIAL, SUCH AS NATURAL OR SYNTHETIC RUBBER; CORRECT?

A. THAT'S CORRECT.

Q. AND YOUR POINT WAS THAT: I LOOK AT OUR INVENTION; WE'RE USING AN IRRADIATED MODIFIED POLYOLEFIN, AND THAT DOESN'T EXPAND IN AN UNCONTROLLED MANNER; WHEREAS THIS '873 PATENT IS USING A NATURAL OR SYNTHETIC RUBBER BALLOON, AND THAT CAN EXPAND IN AN UNCONTROLLED MANNER.

WOULDN'T YOU AGREE?

A. I CERTAINLY WOULD AGREE.

Q. OKAY. AND SO THAT WAS — THAT WAS A DIFFERENCE THAT YOU WERE POINTING OUT BETWEEN THE MATERIAL OF CONSTRUCTION THAT YOU USED; NAMELY, THE IRRADIATED MODIFIED POLYOLEFIN, VERSUS THE MATERIAL OF CONSTRUCTION THAT THE '873 PATENT USED; NAMELY, NATURAL OR SYNTHETIC RUBBER.

A. THAT'S CORRECT.

Q. OKAY. IN FACT, DO YOU RECALL WRITING A PAPER ... DO YOU RECALL WRITING A PAPER ON YOUR ... CATHETER ASSEMBLY IN NINETEEN ... EIGHTY-ONE?

A. YES.

Q. I'M GOING TO HAND YOU WHAT'S BEEN MARKED AS EXHIBIT 25.

(DOCUMENTS HANDED TO THE WITNESS.)

A. (PAUSE)

YES, UH-HUH.

Q. NOW, THAT DESCRIBES A TECHNIQUE IN GENERAL TERMS OF HOW THE BALLOON CAN BE MADE, CORRECT?

A. THAT'S CORRECT.

Q. AND IT ALSO DESCRIBES IN GENERAL TERMS INFORMATION THAT MR. HESS SUPPLIED TO YOU, DOES IT NOT?

A. THAT'S CORRECT, UH-HUH.

Q. NOW, IN THE CATHETER THAT IS DESCRIBED IN YOUR PATENT, FIGURE 4, WHEN THIS IS THE OUTER TUBE IS SHRUNK FIT ONTO THE SMALLER TUBE, IS THAT ... A BONDED RELATIONSHIP IN YOUR MIND?

A. IT'S WATER TIGHT.

Q. WELL, THAT IS NOT QUITE WHAT I ASKED YOU.

A. I SEE.

I MISUNDERSTOOD THE QUESTION.

Q. IS IT BONDED? IS THE OUTER TUBE BONDED TO THE INNER TUBE TO YOUR WAY OF THINKING?

A. NO.

Q. NOW, THE MATERIALS THAT YOU USED BEFORE MR. HESS ENTERED THE PICTURE, NAMELY, PVC AND TEFLON, DO YOU HAVE ANY INFORMATION, DR. SIMPSON, AS TO WHETHER OR NOT THOSE ARE CRYSTALLINE MATERIALS?

A. MY SUSPICION IS THEY ARE NOT, BUT I DON'T KNOW.

Q. OKAY.

I WOULD LIKE TO HAND YOU ALSO WHAT'S BEEN MARKED AS

FOR POLYMER THAT WOULD WORK FOR US.

Q. THAT'S RIGHT.

A. AND SO WE FOUND THROUGH MR. HESS THAT THE RAYCHEM POLYMER REALLY WOULD WORK FOR US QUITE NICELY.

AND THIS IS SORT OF THE WAY IT WAS CHARACTERIZED.

Q. OKAY. AND SO REALLY WHERE YOU WERE AT THE TIME YOU MET MR. HESS WAS YOU KNEW WHERE YOU WANTED TO GO, BUT YOU DIDN'T HAVE ANY WAY UNTIL HESS CAME ALONG TO GET THERE.

A. WE DIDN'T HAVE THE RIGHT MATERIAL TO GET THERE. THAT'S CORRECT.

Q. OKAY.

NOW, YOU TALKED TO MR. HESS ABOUT QUITE A RANGE OF SUBJECTS, DIDN'T YOU, FROM NOT ONLY THE CRYSTALLINE MODIFIED POLYOLEFINS, BUT WHETHER YOU OUGHT TO CONSIDER A BIG COMPANY OR A SMALL COMPANY TO SELL YOUR CATHETER?

A. THAT'S CORRECT.

Q. YOU TALKED TO HIM ABOUT REGULATORY ISSUES.

A. THAT'S CORRECT.

Q. IN FACT, CAN YOU THINK OF ANY SUBJECT AREA THAT WAS RELATED TO YOUR CATHETER THAT YOU DID NOT DISCUSS WITH MR. HESS, APART FROM APPLYING FOR A PATENT?

A. I'M NOT SURE THAT WE DIDN'T DISCUSS APPLYING FOR A PATENT WITH MR. HESS.

ALL I — I DO NOT SPECIFICALLY RECALL THAT WE HAD THOSE DISCUSSIONS, BUT IT BOGGLES MY MIND THAT WITH ALL OF THE

DIDN'T HAVE THE INFORMATION YOU NEEDED TO GET TO THE POINT THAT YOU WANTED TO BE AT?

A. I THINK THAT OUR MEETINGS WITH ROB HESS, OR AT THAT TIME WE WERE TRYING TO EXPLORE DIFFERENT TYPES OF TUBING.

WE HAD BEEN — IT HAD BEEN BROUGHT TO OUR ATTENTION THAT HEAT-SHRINKABLE TUBING MAY BE SOMETHING THAT WE COULD USE. WE WANTED TO EXPLORE THAT AVENUE.

Q. OKAY.

BUT MY QUESTION TO YOU WAS A LITTLE DIFFERENT, DR. ROBERT.

WOULDN'T IT BE ACCURATE TO SAY THAT AT THE TIME JUST PRIOR TO THE TIME THAT YOU HOOKED UP WITH MR. HESS, THAT YOU KNEW WHAT YOU WANTED, BUT YOU DIDN'T KNOW HOW TO GET THERE IN TERMS OF THE MATERIALS?

A. WE WERE — WE WERE UNCERTAIN AS TO WHAT THE OPTIMAL MATERIAL WOULD BE AT THAT TIME, THAT'S CORRECT.

Q. IN FACT, THE ONLY TWO MATERIALS THAT YOU HAD WORKED WITH TO SPEAK OF WERE TEFLON AND PVC, AND NEITHER ONE OF THOSE MET YOUR NEEDS; ISN'T THAT CORRECT?

A. NEITHER ONE WAS OPTIMAL.

Q. IN FACT, THEY DIDN'T MEET YOUR NEEDS AT ALL, DID THEY?

A. TO THE EXTENT THAT WE CARRIED THEM, NO THEY DID NOT.

Q. SO YOUR PURPOSE IN GOING TO MR. HESS WAS TO SEEK SOME ASSISTANCE IN FINDING THE MATERIAL THAT WOULD WORK, HAVING FAILED TO FIND A WORKABLE MATERIAL WITH EITHER TEFLON OR PVC;

EXCERPT FROM PLAINTIFF'S TRIAL EXHIBIT NO. 25

A NEW CATHETER SYSTEM FOR CORONARY ANGIOPLASTY

John B. Simpson, PhD, MD, FACC
Donald S. Baim, MD
Edward W. Robert, MD, FACC
Donald C. Harrison, MD, FACC

Stanford, California

A new catheter system has been designed for percutaneous transluminal coronary angioplasty. An independently movable, flexible-tipped guide wire within the balloon dilation catheter facilitates selection of the involved vessel. This guide wire can be passed slowly and carefully beyond the coronary stenosis, permitting safe advancement of the balloon catheter. After testing in animal and cadaver hearts, this system was used in 53 patients (56 stenoses) with single vessel coronary artery disease, with an overall primary success rate of 64 percent. In the last 41 of these 56 cases, use of a balloon catheter with a smaller deflated diameter increased the success rate to 73 percent. In patients with lesions of the left anterior descending coronary artery, the success rate was 89 percent. Three (6 percent) of the 53 patients had complications during coronary arterial dilation that necessitated emergency coronary arterial bypass graft surgery. There were no procedure-related or late cardiac deaths. During the mean follow-up period of 8 months (range 1 to 21), there were one late death (of noncardiac causes) and no late myocardial infarctions. Clinical status was persistently improved in 31 of the 36 patients who had successful dilation. The remaining five patients experienced restenosis at the angioplasty site and return of angina pectoris within 3 months of dilation. Two of these patients had repeat coronary angioplasty with restoration of asymptomatic status, and three had elective coronary bypass graft surgery.

Transvascular intervention for the treatment of occlusive atherosclerotic peripheral vascular disease was originally introduced by Dotter and Judkins[1] and modified for use in the coronary arteries by Grüntzig et al.[2,3]. It is achieving increasing acceptance as a treatment for coronary artery disease in selected patients, with more than 1,000 cases reported in the National Institutes of Health Registry.[4]

Until recently, only the Grüntzig design of coronary arterial angioplasty catheters was available. In this design the guide wire is fixed to the tip of the balloon dilation catheter, precluding changes in the length or curvature of the guide wire after the catheter has been introduced into the coronary artery. Using a coaxial design and unique materials, we developed a fundamentally different dilation catheter system that permits independent movement and repetitive reshaping of this guide wire. This report described the basic components and techniques used to perform percutaneous transluminal coronary angioplasty with this new system and the clinical experience with our initial 53 patients.

MATERIALS

Five main components (Fig. 1) are included in the Simpson-Robert™ Vascular Dilation System (Advanced Cardiovascular Systems, Inc., Santa Clara, California). All components, including the balloon dilation catheter, are sterilized with routine gas sterilization procedures.

1. *The balloon dilation catheter (Fig. 2)* is manufactured from two concentric pieces of polyolefin tubing. The outer member is contiguous with the balloon wall and provides a deflated balloon diameter of 0.041 inch (1.04 mm). The inner member accepts a 0.018 inch (0.46 mm), Teflon®-coated, flexible-tipped guide wire. Clearance between the inner and outer members provides a channel for injection of contrast medium during balloon inflation and deflation. While the catheter is being filled

with contrast medium, a stainless steel hypodermic tubing is located within this channel to allow egress of displaced air from the balloon tip. When filling is completed, the hypodermic tubing is removed from the catheter.

From the Stanford University Medical Center, Cardiology Division, Stanford, California. Manuscript received May 4, 1981; revised manuscript received October 26, 1981, accepted October 29, 1981.

Address for reprints: John B. Simpson, PhD, MD, 750 Welch Road, Suite 120, Palo Alto, California 94304.

TYPESET VERSION OF PLAINTIFF'S TRIAL EXHIBIT NO. 31

STANFORD UNIVERSITY MEDICAL CENTER
Stanford, California 91305 * (415) 497-6141

Stanford University Hospital
Cardiology Division

April 11, 1978

Mr. Paul M. Cook, President
Raychem Corporation
300 Constitution Drive
Menlo Park, California 94025

Dear Mr. Cook:

As Postdoctoral Fellows in Cardiology at Stanford Medical Center, we have recently been challenged to design and construct a small balloon-tipped catheter for use in treating coronary artery disease. After weeks of frustration because of unsuccessful attempts to obtain assistance or advice from any of the Bay Area plastics firms, we were introduced to Mr. Rob Hess. His advice, frequently requested at unusual hours and often interrupting his weekend at home, has been tireless and critically important to our progress.

Rob introduced us to Raychem modified irradiated polyolefins, suggested numerous approaches to construction, searched diligently for special extrusions that would meet our dimensional requirements, and provided us with more than sufficient samples to construct our prototypes. All of this was done with a genuinely concerned and helpful attitude which has made our brief association with Raychem exciting and productive, and most importantly, it has led to what we consider a device which may well revolutionize the treatment of coronary artery disease in the United States.

The technique is one whereby arteriosclerotic narrowings in coronary arteries (the condition responsible for heart attacks and most instances of sudden death) are dilated by a small balloon-tipped catheter. This catheter is inserted into the anesthetized major artery of the leg and advanced by a guiding system into the coronary arteries. Once the balloon is positioned in the narrowed area, it is hydrolically expanded to compress the atherosclerotic material against the vessel wall and thus open the coronary artery. The technique is experimental but shows great promise and may present an alternative to open heart surgery in selected patients.

The only other catheters presently available for this purpose are manufactured on a small scale in Zurich, Switzerland and because of technically cumbersome assembly they are difficult to obtain in any quantity. Furthermore these catheters have several limitations rendering them far from ideal for their purpose. With Rob's help and using only Raychem materials we have constructed a catheter which has sophisticated performance characteristics while simple to manufacture.

We have enclosed photographs of the prototype catheter and an x-ray demonstrating the catheter inflated in a coronary artery of a cadaver heart. The catheter has a coaxial design; both inner and outer members are made of RNF 100 Type II. Although the initial tubing dimensions varied slightly from our specifications, we have been able to alter them accordingly with judicious heating and stretching over a mandril. Preliminary evaluation of the catheter by physicians and scientists familiar with the dilating technique confirms our feeling that our catheter is far superior to anything currently available and likely to be the catheter of choice in the future.

Although the future of the dilating procedure in general and of our catheter in particular remains modestly speculative, we feel that our endeavors to date reflect a successful meld of your

progressive, open-minded, scientifically oriented corporation with our awareness of the desired end results.

We did not want Rob's unselfish assistance to go unnoticed. Furthermore, as manufacture of the catheter system on a larger scale becomes more likely, we look forward to an even closer relationship with your firm in the future.

Our thanks again to Rob Hess and Raychem for assistance and support.

Sincerely,

/s/ John Simpson

John Simpson, M.D.

/s/ Edward Robert

Ned Robert, M.D.
Senior Postdoctoral Fellows
Cardiology Division
Stanford Medical Center

JS:mc
Enclosures
CC: Mr. R. M. Halperin

TYPESET VERSION OF PLAINTIFF'S TRIAL EXHIBIT NO. 52

REEXAMINATION
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE REEXAMINATION OF U.S. PATENT 4,323,071 ISSUED: APRIL 6, 1982 PATENTEE: JOHN B. SIMPSON AND EDWARD W. ROBERT FOR: VASCULAR GUIDING CATHETER ASSEMBLY AND VASCULAR DILATING CATHETER ASSEMBLY AND A COMBINATION THEREOF AND METHODS OF MAKING THE SAME	Reexamination No. 90/001,327 Examiner: Trulock Art Unit 336 Los Angeles, CA 90010

DECLARATION OF JOHN B. SIMPSON, M.D.

Hon. Commissioner of Patent and Trademarks
Washington, D.C. 20231

I, John B. Simpson, M.D. declare:

1. I am a physician in the field of interventional cardiology, and am in private practice in Palo Alto, California with Cardiovascular Medicine, a medical partnership. I was one of the founders of Advanced Cardiovascular Systems, Inc. ("ACS"). Currently, I am a consultant to ACS.

2. My educational background includes a B.S. Degree from Ohio State University, M.S. and Ph.D. Degrees from the University of Texas, and an M.D. from Duke University. My medical internship and residency were done at Duke University Hospital, and I was a fellow in cardiology for two years (1976-1978) at Stanford University School of Medicine.

3. Commencing in the fall of 1978 and continuing to the present date, I have performed a large number of percutaneous transluminal coronary angioplasty (PTCA) procedures on human patients. In this same time period, I have co-authored a number of publications and made numerous presentations to medical groups on PTCA throughout the United States and in Europe and Japan. Additionally, since 1980 I have regularly demonstrated PTCA procedures to other physicians from throughout the world, and have held teaching positions at Duke University School of Medicine and Stanford University School of Medicine where I lectured on PTCA. In 1987, I was awarded the Andreas Gruntzig award from the European Cardiology Society based on my work on PTCA.

4. I am co-inventor with Dr. Edward W. Robert on U.S. Patent No. 4,323,071 ("Simpson-Robert patent"). Confronted with a need for access to a dilatation catheter for the purpose of doing experimental studies, Dr. Robert and I set out in early 1978 to develop a suitable catheter. Our intent was to provide a catheter that had the characteristics of a low balloon profile, flexibility in the balloon region, the ability to rapidly inflate and deflate, and a balloon that would inflate to a reliably predictable size and shape and withstand the relatively high pressure needed for a PTCA procedure. It was by no means crucial to our work to have a one-piece balloon tube construction, although we worked primarily with single piece devices because they were easier to make.

5. The success we achieved in our early development work lead us to contact an attorney, in early 1978, for the purpose of preparing and filing a patent application. Such an application was filed on our behalf on May 19, 1980 and ultimately issued on April 6, 1982 as U.S. Patent No. 4,323,071.

6. I am aware of U.S. Patent No. 4,024,873 to Antoshkiw considered during the pendency of the subject reexamination. The

catheter disclosed in the Antoshkiw patent is far removed and not relevant to our invention. I have no recollection of ever believing otherwise and am firmly convinced in light of what is shown and described in Antoshkiw that I would not have ever believed otherwise at any time.

7. The Antoshkiw patent relates to a diagnostic catheter and, more particularly, to a so-called thermo-dilution catheter for determining cardiac output. The catheter assembly disclosed has concentric tubes with a balloon attached at its proximal end to the outer tube and at its distal end to the inner tube. As may be seen in the drawings (compare Figs. 1 and 2 of the Antoshkiw), the balloon is made of a stretchable material such as "natural or synthetic rubber." Provision is made for moving the inner and outer tubes relative to each other to change the shape of the balloon. An inner catheter assembly with a balloon tip is used for flow directing the catheter through the arterial system.

8. There is no doubt that the Antoshkiw type of catheter is totally unsuitable for use in angioplasty procedures. Attempted use would likely cause serious damage to the artery wall without achieving any desired effects. Sufficient force to dilate a plaque cannot be generated in a balloon made of stretchable material. Such a balloon would simply expand and deform around plaque potentially causing damage to the arterial wall. Moreover, with such a balloon or with relatively moveable inner and outer tubes, predictable balloon size and shape are not achieved.

I declare under penalty of perjury that the foregoing is true and correct. Executed at San Francisco, California on February 1, 1989.

/s/ John B. Simpson

JOHN B. SIMPSON, M.D.

Supreme Court, U.S.
FILED

961857 MAY 19 1997

OFFICE OF THE CLERK

No. 97-

IN THE

Supreme Court of the United States

OCTOBER TERM, 1997

ROBERT L. HESS,

Petitioner,

v.

ADVANCED CARDIOVASCULAR SYSTEMS, INC.,

Respondent.

ADVANCED CARDIOVASCULAR SYSTEMS, INC.,

Respondent,

v.

SCIMED LIFE SYSTEMS, INC.,
and
ROBERT L. HESS,

Petitioner.

Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

APPENDIX B

KEITH V. ROCKEY*
KATHLEEN A. LYONS
Dressler, Rockey, Milnamow & Katz, Ltd.
180 North Stetson Avenue
Suite 4700
Chicago, Illinois 60601
(312) 616-5400

Counsel for Petitioner

*Counsel of Record

19 pp

United States Patent [19]

Simpson et al.

[11] **4,323,071**

[45] **Apr. 6, 1982**

[54] **VASCULAR GUIDING CATHETER ASSEMBLY AND VASCULAR DILATING CATHETER ASSEMBLY AND A COMBINATION THEREOF AND METHODS OF MAKING THE SAME**

[75] Inventors: **John B. Simpson**, Menlo Park; **Edward W. Robert**, Los Altos, both of Calif.

[73] Assignee: **Advanced Catheter Systems, Inc.**, Santa Clara, Calif.

[21] Appl. No.: **151,175**

[22] Filed: **May 19, 1980**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 123,713, Feb. 21, 1984, abandoned, which is a continuation of Ser. No. 899,061, Apr. 24, 1978, abandoned.

[51] **Int. Cl.**³ **A61M 29/00**; A61M 25/00

[52] **U.S. Cl.** ..... **128/343**; 128/349 B; 128/DIG. 9; 128/DIG. 18

[58] **Field of Search** ..... 128/656, 657, 658, 679, 128/692, 772, 214.4, 325, 341-344, 347-349 R, 349 B, DIG. 9, 16, 18

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Die Perkutane Transluminale Rekanalisation Chronisher; A. Gruntzig; Witzstrock, N.Y. 77, Ch. 2 and 5.

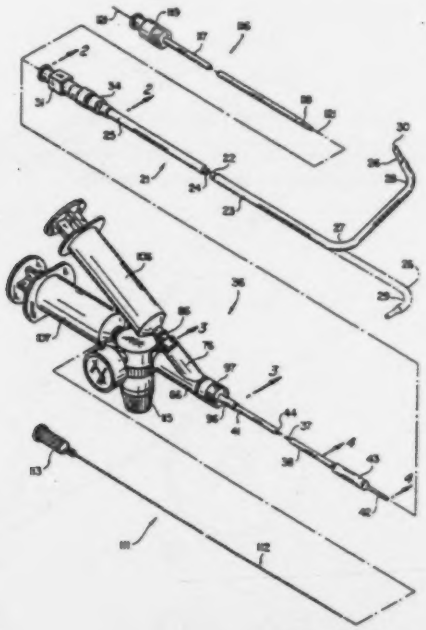
Thermofit Heat Shrinkable Tubing, Raychem 9/77.

Primary Examiner—C. Fred Rosenbaum

[57] **ABSTRACT**

A combination guiding catheter assembly and a dilating catheter assembly. The guiding catheter assembly includes a first flexible tubular member formed of a material which has a low coefficient of friction and a second flexible tubular member encasing said first tubular member so that the first tubular member fits tightly in the second tubular member. The combined first and second tubular members have proximal and distal ends with a fitting mounted on the proximal end. The dilating catheter assembly includes a flexible tubular member. The tubular member of the dilating catheter assembly having proximal and distal ends and an inflatable annular portion formed integral with the tubular member of the dilating catheter assembly near the distal end thereof. A fitting is mounted on the proximal end of the tubular member of the dilating catheter assembly. The dilating catheter assembly is disposed within the guiding catheter assembly. An inflator is provided for inflating and deflating the inflatable annular portion.

21 Claims, 21 Drawing Figures



U.S. Patent Apr. 6, 1982 Sheet 1 of 4 4,323,071

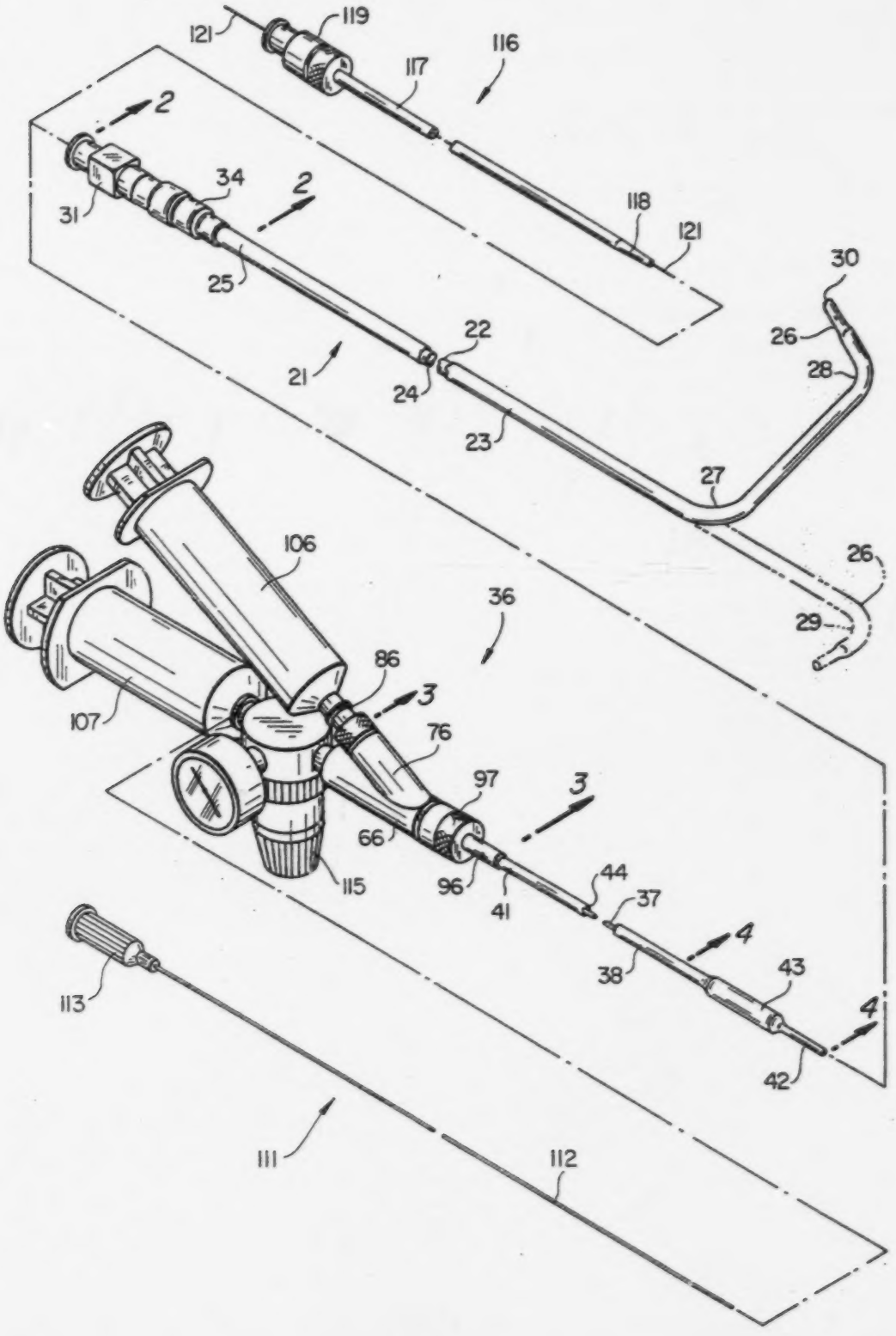


FIG__1

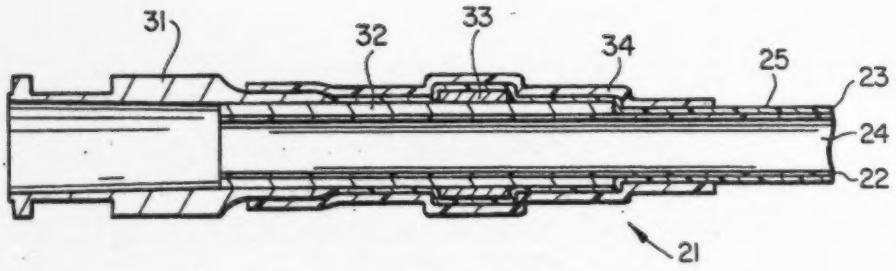


FIG_2

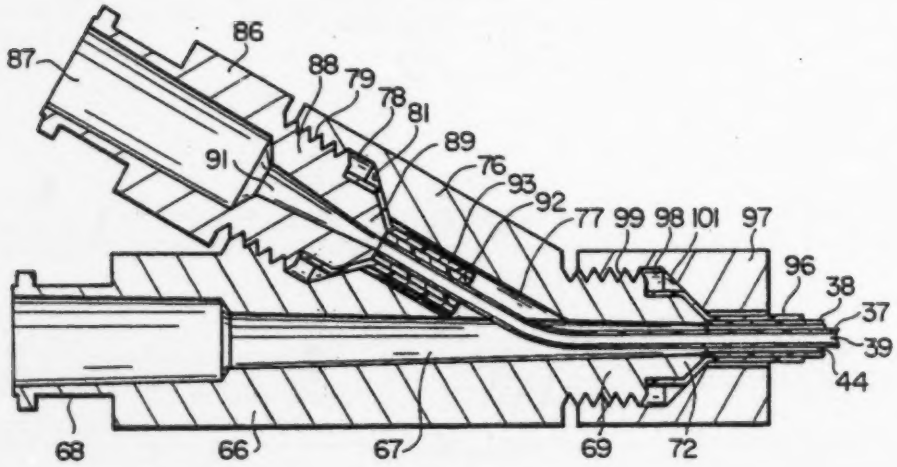


FIG_3

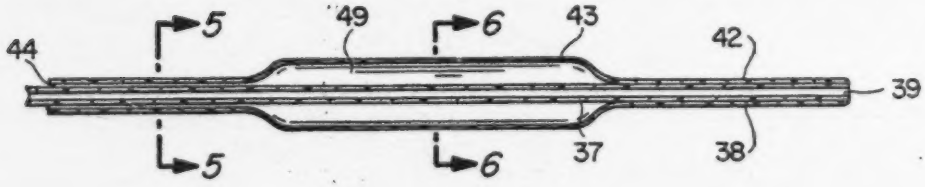


FIG_4

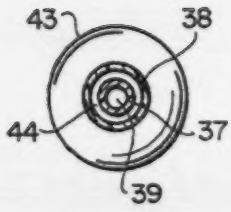


FIG_5

FIG_6A

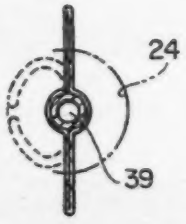


FIG_6B

FIG_7A

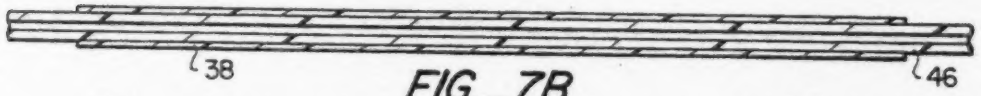


FIG_7B

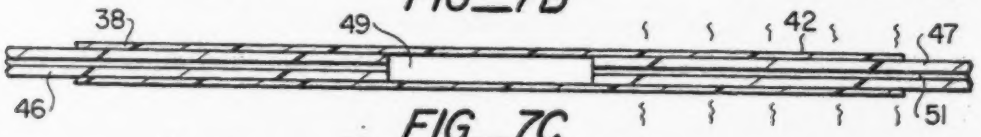


FIG_7C

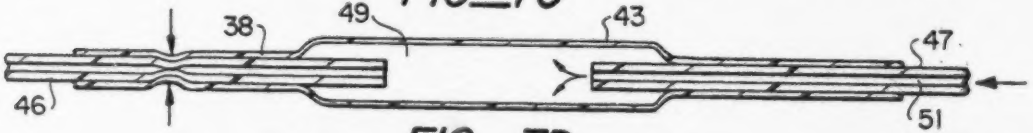


FIG_7D

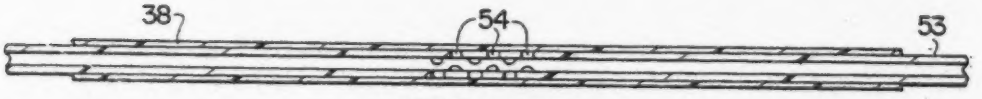


FIG_8A

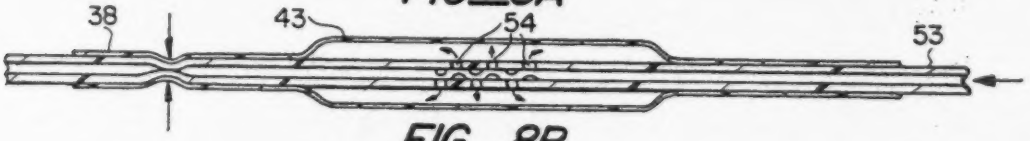


FIG_8B

FIG_9A

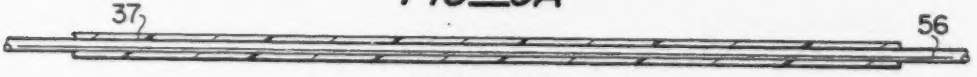


FIG_9B

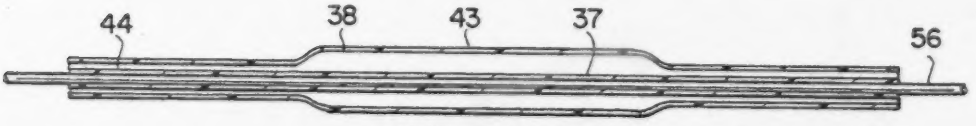


FIG_10A

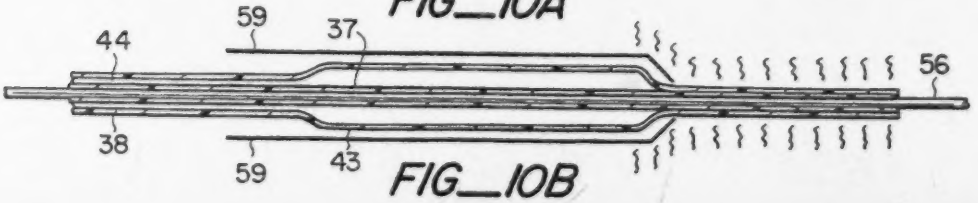


FIG_10B

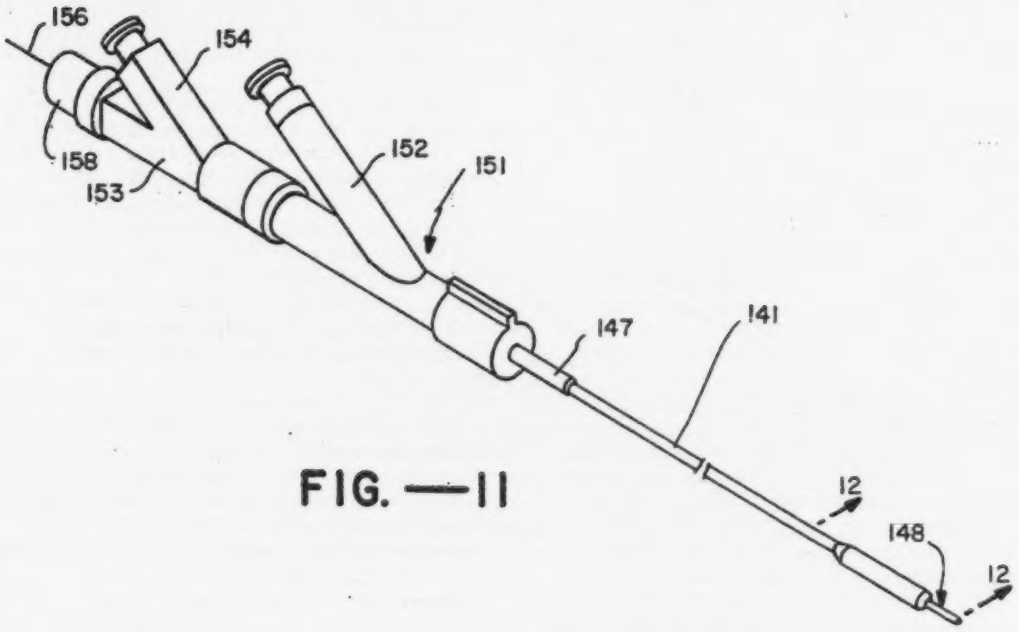


FIG.—11

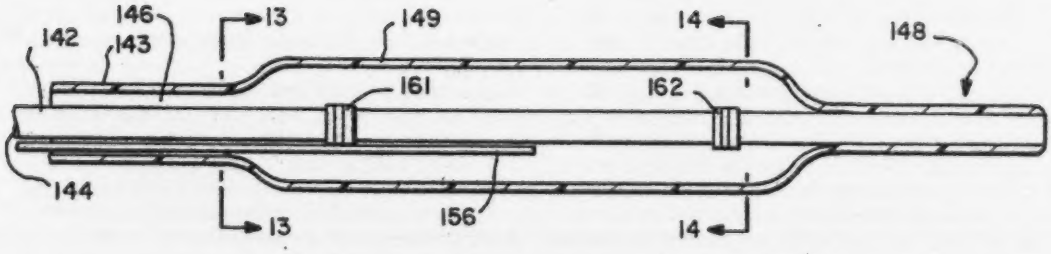


FIG.—12

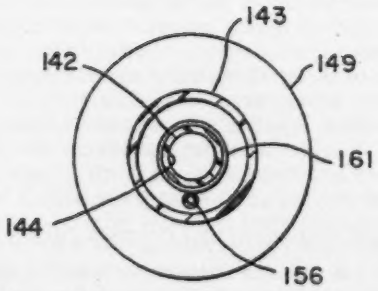


FIG.—13

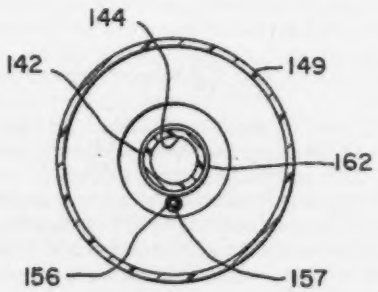


FIG.—14

VASCULAR GUIDING CATHETER ASSEMBLY AND VASCULAR DILATING CATHETER ASSEMBLY AND A COMBINATION THEREOF AND METHODS OF MAKING THE SAME

This application is a continuation-in-part of application Ser. No. 123,713 filed Feb. 21, 1980 which is a continuation of application Ser. No. 899,061, filed on Apr. 24, 1978, both of which are abandoned.

BACKGROUND OF THE INVENTION

As disclosed in the following three references:

1. Grüntzig, A.: Die perkutane transluminale Rekanalisation chronischer Arterienverschlüsse mit einer neuen Dilationstechnik; p. 50. Baden-Baden, 1977.
2. Grüntzig, A., H. H. Riedhammer, M. Turina, Rutishauer W. Verh. Dtsch. Ges. Kreislaufforschg. 1976, 42 282.
3. Grüntzig, A., R. Myler, E. Hanna, Turina M. Abstracts Circulation. 1977 56 84.

a technique has been developed for percutaneous transluminal coronary angioplasty. This technique consists of a catheter system introduced via the femoral artery under local anesthesia. A preshaped guiding catheter is positioned into the orifice of the coronary artery and through this catheter a second dilation catheter is advanced into the branches of the coronary artery. The dilation catheter has an elliptical-shaped distensible balloon portion near the tip which can be inflated and deflated. After traversing the stenotic lesion of the coronary artery, the distensible portion is inflated with fluid which compresses the atherosclerotic material in a direction generally perpendicular to the wall of the vessel thereby dilating the lumen of the vessel. Peripheral arterial lesions treated by this technique have demonstrated by morphological studies that the atheroma can be compressed leaving a smooth luminal surface noted at the time of restudy. The patency rate two years following dilation of iliac and femoropopliteal atherosclerotic lesions was greater than 70%. The continued success of this technique could greatly widen the horizons for coronary angiography and provide another treatment for patients with angina pectoris.

The guiding and dilating catheters utilized by Gruntzig in this work have been more or less hand made. They have been difficult and expensive to fabricate and for that reason it has been very difficult to obtain an adequate supply of the same. There is therefore a need for a new and improved guiding and dilation catheters and methods for making the same.

SUMMARY OF THE INVENTION AND OBJECTS

To perform coronary percutaneous transluminal angioplasty, vascular guiding and dilating catheters must be provided. The present invention is directed to a guiding catheter assembly and dilating catheter assembly and methods for making the same so that they have the desired characteristics and so that they can be made uniformly and without undue expense with volume production being possible.

In general, it is an object of the present invention to provide a guiding catheter assembly which has a very low coefficient of friction so that a dilating catheter assembly can be readily inserted into the same.

Another object of the invention is to provide a guiding catheter assembly of the above character which has sufficient rigidity so that it can be readily manuevered.

Another object of the invention is to provide a method for making the guiding catheter assembly which utilizes heat-shrinkable tubing in the form of an irradiated modified polyolefin for providing the additional rigidity required.

Another object of the invention is to provide a dilating catheter assembly which can be readily inserted through the guiding catheter assembly.

Another object of the invention is to provide a dilating catheter assembly of the above character in which an inflatable or distensible balloon-like portion is formed integral with one of the tubular members forming the dilating catheter assembly.

Another object of the invention is to provide a dilating catheter assembly of the above character in which the balloon-like portion can be readily and reliably formed.

Another object of the invention is to provide a dilating catheter assembly of the above character in which the balloon can be readily inflated with a radiographic contrast liquid and can be rapidly deflated.

Another object of the invention is to provide a dilating catheter assembly of the above character which can be readily inflated with a radiographic contrast liquid being flushed out of the balloon as it is being filled.

Another object of the invention is to provide a method for forming the dilating catheter assembly which utilizes heat-shrinkable tubing for the formation of the balloon-like portion and for forming the passage leading to the balloon.

Another object of the invention is to provide a dilating catheter assembly of the above character in which the catheter is formed of an irradiated modified polyolefin tubing.

Another object of the invention is to provide a dilating catheter assembly of the above character in which inner and outer coaxial tubular members are provided and in which a distal pressure seal is formed between the inner and outer tubular members solely by heating the outer heat shrinkable tubular member.

Another object of the invention is to provide a method for making a dilating catheter assembly in which the balloon-like portion can be readily and easily formed.

Another object of the invention is to provide a method for making a dilating catheter assembly which is reliable and which lends itself to quantity production.

Another object of the invention is to provide a method for inflating the balloon of the dilating catheter assembly with a radiographic contrast liquid and venting any air in the balloon out of the balloon by utilizing a separate flow passage for the escape of air.

Additional objects and features of the invention will appear from the following description in which the preferred embodiments are set forth in detail in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a dilator, a guiding catheter assembly, a dilating catheter assembly and a balloon flushing tube and showing the manner in which they are used with respect to each other and incorporated into assemblies for performing coronary percutaneous transluminal angioplasty.

FIG. 2 is a cross-sectional view taken along the line 2—2 of the guiding catheter assembly.

FIG. 3 is a cross-sectional view taken along the line 3—3 of the dilating catheter assembly.

FIG. 4 is a cross-sectional view taken along the line 4—4 of the dilating catheter assembly.

FIG. 5 is a cross-sectional view taken along the line 5—5 of FIG. 4.

FIGS. 6A and 6B are taken along the line 6—6 of FIG. 5 and show the balloon in inflated and deflated conditions respectively.

FIGS. 7A, 7B, 7C and 7D illustrate the steps utilized in one method for forming the balloon from the irradiated modified polyolefin tubing utilized for the dilating catheter assembly.

FIGS. 8A and 8B illustrate the steps in another method utilized for forming the balloon on the outer catheter of the dilating catheter assembly.

FIGS. 9A and 9B show the steps utilized in the method for forming the inner catheter of the dilating catheter assembly.

FIGS. 10A and 10B show the steps in the method of inserting the inner tubular member into the outer tubular member having a balloon formed therein and shrinking the distal end of the outer tubular member onto the distal end of the inner tubular member to provide an air-tight adhesive-free seal and providing a flow passage through which fluid can be introduced into the balloon for inflating the same and withdrawing it from the balloon for deflating the same.

FIG. 11 is an isometric view of another embodiment of our dilating catheter assembly incorporating the present invention.

FIG. 12 is a cross-sectional view taken along the line 12—12 of FIG. 11.

FIG. 13 is a cross-sectional view taken from the line 13—13 of FIG. 12.

FIG. 14 is a cross-sectional view taken along the line 14—14 of FIG. 12.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The guiding catheter assembly **21** shown in FIG. 1 consists of first and second coaxial tubular members **22** and **23**. The first tubular member is formed of a material which has an extremely low coefficient of friction as for example TFE Teflon (a tetrafluoroethylene polymer) having a coefficient of friction of approximately 0.02. For the material for the first tubular member, the coefficient of friction can range from as low a value as possible to 0.05. It is also desirable that the material utilized for the first tubular member have a certain amount of flexibility. The first tubular member has a guiding passageway **24** having an internal diameter of approximately 0.075 of an inch. It also can have a suitable wall thickness preferably in the vicinity of 0.004 of an inch. However, these dimensions can vary within the range of approximately ±15% and still be satisfactory.

Although TFE Teflon utilized for the first tubular member was very desirable because it had a very low coefficient of friction, it was found, however, that it was too flexible with thin walls to serve as a guiding catheter because it could not be properly manipulated in the body of the patient. It is for this reason that the second tubular member **23** is provided. This second tubular member is formed of a heat-shrinkable irradiated modified polyolefin supplied by Raychem Corporation of Menlo Park, Cal. The heat shrinkable tubing selected had an internal diameter of 0.120 of an inch which was of a sufficient size so that the first tubular member could be readily inserted into the same. The second tubular member of the assembled first and second tubular members **22** and **23** was then progressively heated along its length in a suitable manner such as by a hot air tool to a suitable temperature as for example 120° C. to cause the second or outer tubular member **23** to shrink in a manner well known to those skilled in the art so that it forms a tight seal with respect to the first tubular member **22**. Alternatively this can be accomplished by passing the assembled first and second tubular members through a cylindrical heating unit to cause progressive heating of the second tubular member.

The assembly is provided with proximal and distal ends **25** and **26**. The distal end is provided with bends to form a shape identical to the standard coronary catheter. A left coronary guiding catheter is formed by providing two bends **27** and **28** of approximately 120°–150° (proximal) and 60°–90° (distal) each in the same direction to provide the bends which are shown in FIG. **1** for a left coronary artery. As soon as the bends **27** and **28** have been formed, the distal end can be cut off to the desired length and thereafter, the distal end can be sanded or smoothed in a suitable manner. An annular recess **30** is formed on the extreme distal end of the tubular member **23**. For a right coronary guiding catheter a single bend **29** as shown by the broken lines in FIG. **1** can be provided.

An attachment or fitting **31** is secured to the proximal end of the first and second tubular members in a suitable manner. The attachment or fitting **31** is in the form of a female Luer fitting or attachment having a metal cylindrical extension **32** on which there is crimped a metal band **33**. The first or inner tubular member **22** is inserted into the cylindrical extension **32** and the second or outer tubular member **23** is slipped over the cylindrical extension **32** and the band **33**. A sleeve **34** also formed of a similar heat-shrinkable tubing is thereafter slid over the outer or second tubular member **23** and the fitting **31**. The sleeve **34** is then heated to a suitable temperature as for example 120° C. to cause it to shrink over the fitting **31** and also over the proximal end of the first and second tubular members **22** and **23** to form an excellent leakproof adhesive-free connection between the parts.

The material which is utilized for the second tubular member **23** has a substantially higher coefficient of friction than the material utilized for the first tubular member **22**. However, this is not objectionable since the second tubular member will be inserted into the blood vessel over a wire in a standard percutaneous technique and thus will be lubricated by the blood in the vessel. The use of the guiding catheter assembly will be described in conjunction with the dilating catheter assembly hereinafter described.

The guiding catheter assembly **21** has a suitable length which is tailored to the purpose for which it is used. As for example, when utilizing the same for doing coronary percutaneous transluminal angioplasty on adults, a length of 95–110 cm. is utilized.

The dilating catheter assembly **36** as shown in FIG. **1**, consists of first and second tubular members **37** and **38**. The first and second tubular members **37** and **38** are formed of heat-shrinkable tubing of the type hereinbefore described manufactured by Raychem Corporation of Menlo Park, Cal. The first tubular member **37** is provided with a flow passage **39** extending the length of the same. The first tubular member **37** is coaxially dis-

posed within the second tubular member in such a manner so that the second tubular member surrounds the first tubular member. The combined first and second tubular members 37 and 38 have a proximal end 41 and a distal end 42. The second tubular member 38 has formed therein a balloon-like or inflatable annular portion 43 near the distal end 42 of the first and second tubular members 37 and 38. An annular flow passage 44 is formed between the second tubular member 38 and extends from the proximal end into the balloon-like or inflatable annular portion 43 to permit the introduction of fluid into the balloon-like portion 43 for inflating the balloon-like portion and for withdrawing fluid from the same for deflating the balloon-like portion.

The method by which the assembly consisting of the first and second tubular members 37 and 38 with the balloon-like portion 43 and the passages 39 and 44 formed therein is manufactured can be seen by reference to FIGS. 7A through 7D. The second tubular member 38 has an initial inside diameter of 0.065 inches and an initial outside diameter of 0.085 inches. As is well known to those skilled in the art, the manufacture of heat-shrinkable tubing is accomplished by extruding a modified polyolefin to a predetermined size and utilizing high energy ionizing radiation to cause cross-linking of the polymer chains to occur. Thereafter, the tubing is expanded to a suitable ratio such as 2:1. A mandrel 46 in the form of a Teflon tube is inserted into the tubular member 38 as shown in FIG. 7A. The member 38 is then progressively heated as shown in FIG. 7B to shrink the member 38 down onto the mandrel 46 so that it has an inside diameter of approximately 0.058 inches and an outside diameter of 0.072 inches with a wall thickness of 0.007 inches. The steps shown in FIGS. 7A and 7B are only carried out to provide a tubular member 38 of the desired size. Alternatively this can be accomplished by producing initially a heat-shrinkable tubing of the desired size. The mandrel 46 is withdrawn to the position shown in FIG. 7C and another mandrel 47 in the form of a Teflon tube having an outside diameter of 0.054 inches is placed in the distal end 42. The mandrel 46 extends substantially the entire length of the second tubular member 38 which can have a suitable length ranging from 105 to 120 cm. The mandrel 47 is spaced from mandrel 46 to provide a space 49 through which the balloon-like portion 43 is to be formed. The other mandrel 47 serves as a support for supporting the distal end of the second tubular member 38. The second tubular member 38 is then heated to a suitable temperature as for example 120° C. in the vicinity of the ends of the mandrels 46 and 47 facing the space 49 to shrink those portions of the second tubular member 38 onto the mandrels 46 and 47 to form air-tight seals. The portion of the member 38 encircling the space 49 is then heated until the material reaches a temperature beyond its crystalline melting point. With the mandrel 46 sealed at its proximal end, air under pressure is introduced by suitable means such as a syringe (not shown) through the passage 51 into the space 49 in the tubular member 38 to cause the tubular member to expand to form the balloon-like portion 43 as shown in FIG. 7D. By way of example, air under pressure of 4 to 5 p.s.i. was utilized to form the balloon-like portion 43. Other fluids can be utilized if desired.

The balloon-like portion 43 is formed by expanding that portion of the tubing 38 surrounding the space 49 to its elastic limit which generally corresponds to a ratio of 4 or 5 to 1 from the original extruded irradiated tubing size prior to the initial expansion.

The balloon-like portion 43 thus formed preferably has dimensions ranging in length from approximately 1 to 2 centimeters and an outside diameter ranging from 0.120 to 0.140 inches and a wall thickness ranging from 0.002 to 0.004 inches.

Alternatively the balloon-like portion 43 can be formed as shown in FIGS. 8A and 8B. As shown therein, the mandrel 46 can be removed and another mandrel 53 having holes 54 inserted into the distal end. Heat is then applied to the tubular member on opposite ends of the holes 54 to shrink the tubular member 38 so that it forms air-tight seals with the mandrel 38. The proximal end of the member 38 is clamped and air is introduced into the distal end after the member 38 has been heated in the vicinity of the holes to a temperature beyond the crystalline melting point and a balloon-like portion 43 is formed in the manner hereinbefore described. Thereafter, the mandrel 53 can be removed.

The balloon-like portion is permitted to cool to room temperature while the pressure is maintained in the balloon so that the temperature of the material falls below its crystalline melting point to thereby retain a semi-permanent distensible balloon-like portion 43 within the second tubular member adjacent the distal end thereof. After the balloon-like portion has been sufficiently cooled, the Teflon mandrels 46 and 47 are removed to provide a second or outer sheath.

The first or inner tubular member 37 is formed by taking a tube of heat-shrinkable tubing of the type hereinbefore described having an outside diameter of 0.05 and having an inside diameter 0.030 having a suitable length as for example approximately 110 cm. and placing within the same a Teflon coated guide wire (or a Teflon mandrel) 56 having an outside diameter of 0.021 inches as shown in FIG. 9A. The first tubular member 37 with the guide wire 56 therein which serves as a mandrel is heated to a suitable temperature as for example 125° C. and stretched to cause the first tubular member 37 to shrink down onto the guide wire 56 as shown in FIG. 9B.

The assembly which is shown in FIG. 9B is then taken and inserted into the outer sheath or tubular member 38 which is shown in FIG. 10A. It extends beyond both ends of the outer sheath and passes through the balloon portion 43. The balloon-like portion 43 is then covered with a cover 59 of a suitable type such as aluminum foil for protecting the balloon-like portion 43 from heat. Thereafter, the portion of the second tubular member 38 from the balloon-like portion 43 to the distal end is heated to a suitable temperature as for example 125° C. to cause the outer tubular member 38 to shrink tightly onto the first tubular member 37 with the Teflon guide wire or mandrel 56 therein to provide a fluid tight adhesive-free seal between the first and second tubular members 37 and 38. After the material has cooled, the mandrel 56 is removed to provide the construction hereinbefore described that is, a first tubular member 37 with a flow passage 39 therein and a second tubular member 38 coaxial with tubular member 37 with an annular flow passage 44 therein extending from the proximal end into the balloon portion 43.

The proximal ends of the first and second tubular members 37 and 38 as shown in FIG. 3 are inserted into an adapter body 66. The body 66 is formed of a suitable material such as metal or plastic and is provided with a centrally disposed bore 67 which opens through a fe-

male Luer type fitting 68. The adapter body 66 is also provided with a threaded cylindrical projection 69 and a generally conical portion 72 which projects beyond the threaded projection 69. The adapter body 66 is provided with a side arm 76 which is provided with a cylindrical bore 77 that extends into the bore 67 at a suitable angle as for example an angle of approximately 30°. A well 78 is formed in the side arm 76 and is provided with an internally threaded portion 79 and a conical-shaped recess 81. As shown particularly in FIG. 3, the first or inner tubular member 37 is placed in contact with a fitting 86. The fitting 86 is provided with a cylindrical bore 87. As can be seen, the fitting 86 is in the form of a conventional female-type Luer fitting. The fitting 86 is provided with a threaded projection 88 which engages the internal threads 79. It is also provided with a conical projection 89 which is adapted to seat against the conical recess 81.

In the construction shown in FIG. 3, the inner tubular member 37 is brought into engagement with the inner end of a conical bore 91 provided in the threaded portion 88 and the conical portion 89 of the fitting 86 and is thus in communication with the cylindrical bore 87. Suitable means is provided for maintaining the flow passage 39 in the first tubular member 37 in communication with the conical bore 91 and consists of a heat-shrinkable tubular member 92 which is secured to the proximal end of the first tubular member 37. Member 92 is provided for the purpose of reinforcing the proximal end of the tubular member 37. Another heat-shrinkable tubular member 93 which has a flared outer end is shrunk onto the tubular member 92 and is fitted onto the conical projection 89 and is firmly held in place by threading of the fitting 86 into the side arm 76.

A heat shrinkable tubular member 96 having a flared outer end is secured to the proximal end of the second tubular member 38. The flared outer end of the tubular member 96 is then positioned over the conical portion 72 of the adapter body 66 and is held in place by a collar 97 which is provided with a well 98 having an internally threaded portion 99 and a conical recess 101 against which the conical projection 72 is adapted to seat to firmly grip the flared portion of the tubular member 96.

First and second syringes 106 and 17 are adapted to be placed in the fittings 86 and 68 as shown particularly in FIG. 1. The syringes 106 and 107 are of a conventional type and therefore will not be described in detail.

After the fittings hereinbefore described have been provided on the proximal end of the first and second tubular members 37 and 38, the distal end can be cut to the proper length and then ground to provide a smooth tapered distal end.

The balloon flushing tube 111 which is also shown in FIG. 1 consists of a long tubular member 112 formed of a suitable material such as stainless steel and having a length ranging from 36 to 40 inches. By way of an example, it can have an outside diameter of 0.020 inch and an internal diameter of 0.10 inch. The tubing 112 has its proximal end connected to a conventional female Luer-type fitting 113 formed of a suitable material such as aluminum. The tubular member 112 can be secured to the fitting 113 by soldering or by a crimp fit.

A dilator 116 which is shown in FIG. 1 is of a conventional type and consists of a flexible tube 117 formed of plastic and having a tapered distal end 118 having an outside diameter of 0.080 inches and an inside diameter of 0.040 inches. A female Luer-type fitting 119 is secured to the proximal end of the tube 117. A flexible Teflon coated guide wire 121 of a conentional type with an outside diameter of 0.038 inches is adapted to be inserted through the dilator 116 as shown.

Use of the guiding catheter 21, the dilating catheter 36 and the balloon flushing tube 111 can now be briefly described as follows. Let it be assumed that it is desired to utilize these devices with a middle-aged patient who has been identified as having a significant narrowing in one of the coronary arteries as for example the left anterior descending coronary artery i.e. the proximal portion of that vessel for which a coronary transluminal dilation is considered advisable.

The patient is brought into a sterile environment and is prepared by sterilizing one of the groins. In preparation for operating upon the patient, the dilating catheter assembly 36 is checked. Normally, the dilating catheter assembly 36 would be supplied with the balloon flushing tube 111 in place. However if this is not the case, the balloon flushing tube 111 can be inserted through the passage 44 until it enters into the ballon 43. A syringe (not shown) filled with a radiographic contrast liquid inserted into the fitting 113 and the fluid is introduced into the balloon 43 to fill the balloon at the same time to flush out any air bubbles which may exist in the balloon or in the passage or lumen 44 leading to and from the balloon. The balloon flushing tube 111 can then be removed and as soon as it is removed, a syringe 107 is placed in the fitting 68 and is filled with a radiographic contrast liquid. The operations thus far described have taken place outside the body of the patient. Before inserting the dilating catheter assembly 36 into the body, the inflation and deflation of the balloon 43 can be readily checked merely by operating the syringe 107. A conventional pressure gauge and pressure regulator 115 are provided associated with the syringe 107 so that one can ascertain and limit the pressure being applied to the balloon 43 to approximately 45 to 80 psi.

When this has been accomplished, the guiding catheter 21 can be inserted into the patient in a standard percutaneous technique. The guiding catheter 21 has been designed so that it can enter into one of either the right or left femoral arteries. In such a technique, a needle is inserted into the femoral artery and the Teflon covered guide wire 121 is inserted through the needle and through the femoral artery into the aorta. The movement of the guide wire and positioning thereof is observed with conventional fluoroscopic techniques. It is positioned so that its tip is generally at the level of the diaphragm of the patient which is essentially half way up the aorta. The dilator 116 is positioned in the guiding catheter assembly 21 so that the flexible tapered tip 118 projects from the distal end of the guiding catheter assembly 21.

The distal end of the guiding end of the guiding catheter assembly 21 is then straightened out and the dilator and the guiding catheter 21 are passed over the guide wire which is already in place and is then introduced into the femoral artery. The guiding catheter is then passed up along the guide wire using the guide wire as a guide to the descending aorta or arch of the aorta. During the time that the guiding catheter assembly is being inserted, the operation is under continuous fluoroscopic control. The dilator carried by the end of the guiding catheter assembly is radiopaque and therefore can be easily visualized radiographically. The guiding catheter is inserted until the distal end of the catheter is at the desired point which will generally be in the ascending portion of the aorta several centimeters from

the coronary artery ostium. As soon as the guiding catheter assembly has reached this position, the guide wire and the dilator can be removed from the guiding catheter and the guiding catheter will be aspirated to remove any debris then flushed with radiopaque contrast medium. Thereafter, the catheter can be flushed with a saline solution or contrast medium.

As soon as entry into the blood vessel has been accomplished as hereinbefore described with the guiding catheter assembly **21**, the patient can be given intravenous heparin in a standard dose to act as an anticoagulant and to prevent any abnormal thrombosis or blood clot formation on the catheter or in the areas of catheter entry. The guiding catheter assembly **21** can then be filled with a radiographic contrast material such as Renographin **76** and the catheter can be advanced until it engages into the left main cornary ostium which is the artery to be utilized. The positioning of the guiding catheter can be confirmed by one or more injections of the contrasting liquid into the coronary vessel in which fluoroscopic observations are taking place.

As soon as it has been ascertained that the guiding catheter assembly **21** has been properly positioned in the coronary ostium, the dilating catheter assembly **36** can be inserted. To insert the dilating catheter, the balloon **43** is completely deflated as shown in FIG. **6B**. When it is deflated, it may assume the position shown by broken lines in FIG. **6B** so that the dilating catheter assembly **36** can be readily inserted into the guiding catheter assembly **21**. As hereinbefore explained, since the guiding catheter assembly **21** is formed of a first tubular member which is formed of a material having a low coefficient of friction, it is possible to push the dilating catheter assembly **36** through the entire length of the guiding catheter assembly **21** so that it will protrude out of the distal tip of the guiding catheter assembly by suitable distance such as 5 or 6 cm. and protrude into the left main coronary orifice.

Initially the balloon **43** is positioned in one of the closest portions of the vessel the aorta and then gradually under fluoroscopic control is advanced to the point where the narrowing has been previously documented to exist. The balloon is then appropriately positioned in the narrowed portion.

Although it should be possible in all cases to be able to insert the dilating catherer **36** into the guiding catheter assembly without the help of a guide wire, a small guide wire can be utilized if desired. If such is the case, a small guide wire can be inserted through the sidearm **76** and through the first tubular member **37** so it extends just to the distal portion of the dilating catheter assembly **36** or slightly beyond it. If such guide wire is utilized, after the dilating catheter assembly **36** is in position, the small guide wire can be removed and the syringe **106** having a radiographic contrast liquid therein can be mounted on the side arm **76** and small injections of the contrasting liquid can be introduced into the first inner tubular member **37** through the passage **39** to document the position of the distal end of the dilating catheter assembly **36**. If desired, the guide wire can be reinserted at any time to be used as an aid in guiding the dilating catheter into the vessel that has previously demonstrated that it is subject to a stenosis or narrowing. As soon as it has been established that the balloon **43** has been positioned within the stenosis, pressure can be applied by the use of the hand syringe **107** to inflate the balloon to a suitable pressure as for example from 3 to 5 atmospheres. The inflation of the balloon can be visualized radiographically because the balloon is filled with a radiographic contrast liquid. By way of example, the balloon would be inflated for a period ranging from 2 to 5 second and then deflated rapidly and removed from the stenosis at which time a second coronary contrast injection can be made either through the guiding catheter itself or through the passage **39** of the inner catheter **37**.

As far as can be ascertained, the inflation of the balloon causes dilation of the material deposited in the wall of the vessel by causing elongation of the material along the wall and compressing of the material against the wall so that the end result is an increased blood vessel lumen size with increased blood flow to provide an improved oxygen delivery to the jeopardized portion of the heart muscle or myocardium.

The procedure can be repeated as many times as deemed necessary either on the same site or at a stenosis or narrowing in a second vessel. As soon as the necessary dilations have been completed, the dilating catheter assembly **36** can be removed. Thereafter, the guiding catheter assembly **21** can be removed merely by pulling it out of the femoral artery. As soon as the guiding catheter has been removed, the groin is held firmly to prevent any bleeding until clotting has been accomplished. The patient can then be returned to his room and instructed to remain at bed rest withe the legs straight and flat for approximately six hours after which normal routine activity can be undertaken by the patient.

It should be appreciated that if desired, a dilating catheter assembly **36** can be provided which only utilizes a single tubular member with a balloon near its distal end. When this is the case, the first tubular member **37** can be omitted, and the tubular member which is utilized can be shrunk down to the final desired size onto mandrels prior to formation of the balloon portion.

Another embodiment of the dilating catheter assembly is shown in FIGS. **11–14**. The dilating catheter assembly **141** consists of first and second tubular members **142** and **143**. The first and second tubular members **142** and **143** are formed of heat shrinkable material of the type hereinbefore described manufactured by Raychem Corporation of Menlo Park, California. The first tubular member **142** is provided with a flow passage **144** extending the length of the same. the first tubular member **137** is coaxially disposed within the second tubular member **143** in such a manner so that the second tubular member surrounds the first tubular member. The sizing of the members **142** and **143** is such thar an annular flow passage **146** is provided between the outer surface of the first tubular member **142** and the inner surface of the second tubular member. The combined first and second tubular members **142** and **143** have a proximal end **147** and a distal end **148**.

The second tubular member is provided with a distensible or inflatable annular portion or segment **149** which is adacent the distal end **148**. The dilating catheter assembly **141** is manufactured in a manner very similar to that described for the dilating catheter assembly **36**. Thus, the outer extremities of the members **142** and **143** are fused or bonded together as shown in FIGS. **11** and **12** to provide a fluid tight seal between the outer extremities of the first and second members **142** and **143**. The annular flow passage **146** between the inner surface of the member **143** and the outer surface of the member **142** provides a flow passage which is in communication

with the interior of the inflatable annular portion **149** and the proximal end **147**.

The proximal end **147** of the combined first and second tubular members **142** and **143** is inserted into an adapter body **151** similar to the adapter body **66** with the principal difference being that the adapter body **66** is formed of metal and the adapter body **151** is formed of plastic. The adapter body **151** is provided with a side arm **152**. Another adapter body **153** is mounted on the adapter body **151** and is also provided with a side arm **154**. The side arms **152** and **154** are provided with conventional Luer-type fittings.

In order to facilitate filling of the inflatable annular portion **149** with a radiographic contrast liquid, it is desirable to provide some means for permitting the air flushed from the inflatable annular a portion **149** and the passage leading to the annular portion **149** to exit or be vented to the atmosphere. This is accomplished by inserting a flexible tubular member **156** which can be called a flush tube into the flow passage **146** between the first and second tubular members **142** and **143** so that it is in communication with the interior of the distensible annular portion **149** and also extends out of the proximal end **147** of the combined first and second tubular members **142** and **143** and preferably so that it extends out of the adapter bodies of **151** and **153** as shown in FIG. **11**. The tubular member or flush wire **156** is provided with a flow passage **157** through which air can readily pass when radiographic contrast medium is introduced into the flow passage **146** through port **154**.

It is desirable to have the dilating catheter assembly as small as possible so that it can be readily utilized in human beings. For the same reason it is desirable to make the flush wire or tube as small as possible so that it can fit within a flow passage which is also relatively small. Thus, by way of example, the flush wire can be constructed of a suitable material such as stainless steel and have an inside diameter of 0.004 inches and outside diameter of 0.008 inches.

At the distal end of the dilating catheter assembly, the combined first and second tubular members **142** and **143** are fused and have an outside diameter of 0.035 inches and an inside diameter of 0.023 inches and a wall thickness of 0.006 inches. At the proximal end of the dilating catheter assembly **141**, the outer member has an outside diameter of 0.055 inches and an inside diameter 0.043 inches with a wall thickness of 0.006 inches.

The inner or first tubular member throughout has an outside diameter of 0.034 inches and an inside diameter of 0.023 inches and a wall thickness of 0.0055 inches.

It can be seen from the dimensions given, there is sufficient space in the flow passage **146** to permit the passage of the flush wire **156** therethrough.

In order to facilitate placement of the distensible annular portion during use of the dilating catheter assembly, a pair of spaced apart markers **161** and **162** are provided. As shown, the markers **161** and **162** are formed of a metal ribbon which can be gold that is helically wrapped onto the first or inner tubular member **142** in two positions spaced 1.5 cm. apart, and fixed with a small amount of cyanocylate ester. The two positions correspond generally to the two extremities of the balloon-like portion **149** as shown in FIG. **12**. The gold ribbon can have a suitable dimension such as 0.002 inches and width of 0.010 of an inch with five wraps of the same being utilized to provide a marker.

The adapter body is provided with a fitting **158** which is threaded thereon. The fitting **158** carries a resilient siding member (not shown) disposed within the same and having a small hold therein through which the flush wire **166** extends, When the fitting **158** is threaded onto the adapter **153**, the resilient sealing member is compressed against the flush wire **156** to form a liquid-tight seal between the flush wire **156** and the fitting **158**.

Operation and use of the dilating catheter assembly may now be briefly described as follows: Let it be assumed that the dilating catheter assembly has been assembled in the manner therein described in connection with previous embodiments. The principal difference would be that the markers **161** and **162** would be formed onto the inner tubular member **142** before assembly. After the inner and outer tubular members have been assembled with the adapter **151**, the flush wire or tube **156** can be inserted manually through the adapter **151** through the passage **146** until it extends into the annular portion **149** as shown in FIG. **12**. The adapter **153** can then be placed on the flush wire or tube **156** inserted into the adapter **151**. The fitting **158** can then be positioned onto the flush wire with its sealing member therein and with the flush wire extending therethrough. The fitting **158** is then threaded onto the adapter **153** with the sealing member therein being compressed to form a liquid-tight seal between the flush wire **156** and the fitting **158**. The dilating catheter assembly is ready for packaging and is ready for use in this condition with the flush wire **156** in place.

Let is be assumed that it is now desired to use the dilating catheter assembly in connection with procedures to be performed upon a patient. Before use it is desirable to inflate the balloon with a radiographic contrast liquid. This can be accomplished by taking a syringe (not shown) which can be filled with a radiographic contrast liquid and placing the same onto the side arm **154**. The side arm **152** is covered with a plug (not shown) to prevent escape of liquid therefrom. The syringe is then operated to cause the radiographic contrast liquid in the syringe to pass through the passage **146** into the distensible annular portion **149** to inflate the same. As the radiographic contrast liquid enters the passage **146** and the annular portion **149**, air within the passage **146** and the annular portion **149** is flushed out and is permitted to escape through the flush wire **156** to be vented to the atmosphere. This procedure continuous until the annular portion **149** has been completely filled and is free of air. Since the annular portion **149** is outside of the body, the annular portion **149** can be readily examined visually to ascertain whether or not there are any air bubbles remaining. The use of the flush wire **156** ensures that all air within the balloon portion **149** can escape and be vented readily. In addition, the flush wire **156** facilitates rapid filling of the distensible annular portion **149**.

If it is ascertained that the annular portion **149** has been properly inflated and all air has been flushed from the dilating catheter assembly, the radiographic contrast liquid may be withdrawn from the distensible annular portion to deflate or collapse of the same. Thereafter, the adapter **153** is removed along with the flush wire **156**.

The dilating catheter assembly can be placed in a guiding catheter assembly of the type hereinbefore described where a seal is formed around the dilating catheter assembly while it is in the guiding catheter assembly to prevent leakage of blood out around the guiding catheter assembly and also to permit the pressure of radiographic contrast liquids to be measured in the

guiding catheter during the dilation procedure. The remainder of the procedure is the same as hereinbefore described with the previous embodiment.

It is apparent from the foregoing that there has been provided a vascular dilating catheter and an assembly thereof and method for making the same which makes it possible to fabricate the same utilizing quantity production techniques. The construction of the guiding catheter assembly and the dilating catheter assembly is such that the methods utilized take advantage of heat-shrinkable tubing. The guiding catheter assembly has an interior surface which has a very low coefficient of friction so that the dilating catheter assembly can be readily inserted therethrough. In addition, the guiding catheter assembly has sufficient rigidity so that it can be readily manuevered. The dilating catheter assembly is provided with an inflatable annular portion which is formed integral therewith which can be readily inflated and deflated through an annular passage independently from fluid infusion or pressure measurements through the inner catheter.

What is claimed is:

1. In a combination of a guiding catheter assembly and a dilating catheter assembly, the guiding catheter assembly comprising a first flexible tubular member formed of a material which has a low coefficient of friction, a second flexible tubular member encasing said first tubular member so that the first tubular member fits tightly in the second tubular member, said combined first and second tubular members having proximal and distal ends and a fitting mounted on the proximal ends, the dilating catheter assembly comprising a flexible tubular member, said tubular member of said dilating catheter assembly having proximal and distal ends and an inflatable annular portion formed integral with the tubular member of said dilating catheter assembly near the distal end thereof, a fitting mounted on the proximal end of the tubular member of the dilating catheter assembly, said dilating catheter assembly being disposed within said guiding catheter assembly and means for inflating and deflating said inflatable annular portion.

2. A combination as in claim 1 wherein the second tubular member of said guiding catheter assembly of said guiding catheter assembly has greater rigidity than said first tubular member.

3. A combination as in claim 2 wherein said first tubular member of the guiding catheter assembly is formed of a tetrafluoroethylene polymer.

4. A combination as in claim 1 wherein said first and second tubular members of said dilating catheter assembly are coaxial.

5. In a combination of a guiding catheter assembly and a dilating catheter assembly, a guiding catheter assembly comprising a first flexible tubular member formed of a material which has a low coefficient of friction below 0.05, a second flexible tubular member encasing said first tubular member so that the first tubular member fits tightly in the second tubular member to combine the first and second tubular members, said combined first and second tubular members having proximal and distal ends and a fitting mounted on the proximal end, the dilating catheter assembly comprising first and second tubular members, said first tubular member of said dilating catheter assembly surrounding said second tubular member of said dilating catheter assembly surrounding said second tubular member of said dilating catheter assembly, said first tubular member of said dilating catheter assembly having proximal and distal ends and an inflatable annular portion formed integral with the tubular member near the distal end thereof, means forming a fluid-tight seal between the first and the second tubular members of the dilating catheter assembly in a region between the inflatable annular portion and the distal ends of the first and second tubular members of the dilating catheter assembly, a fitting mounted on the proximal ends of the first and second tubular members of the dilating catheter assembly, means forming a fluid passageway from the proximal ends of the first and second tubular members of the dilating catheter assembly extending into the inflatable annular portion, said dilating catheter assembly being disposed within said guiding catheter assembly and means for inflating said inflatable annular portion with a radiographic contract liquid.

6. In a guiding catheter assembly, a first flexible tubular member formed of a material which has a low coefficient of friction and having a guiding passageway extending therethrough, a second flexible tubular member encasing said first tubular member so that the first tubular member fits tightly in said second tubular member, and so that the second tubular member is coextensive in length with the first tubular member, said second tubular member being formed of a plastic material which is flexible but which has a greater rigidity than said first tubular member so as to provide a catheter assembly with the desired rigidity to permit manuevering of the same, the first and second tubular members having proximal and distal ends the distal ends each having a bend therein, a fitting mounted on the proximal ends to permit access to the passage in the first tubular member and an additional tubular member engaging the fitting and the proximal ends with a shrink fit to form an adhesive-free liquid-tight connection between the fitting and the proximal ends.

7. A guiding catheter assembly as in claim 5 wherein said first flexible tubular member is formed of a tetrafluoroethylene polymer.

8. A guiding catheter assembly as in claim 6 wherein the distal end of the second tubular member is provided with an annular recess.

9. A guiding catheter assembly as in claim 8 wherein the distal end of the second tubular member is provided with an annular recess.

10. In a dilating catheter assembly for use with a radiographic contrast liquid, a flexible tubular member and having proximal and distal ends, said tubular member having an inflatable annular portion formed integral therewith adjacent the distal end and a fitting carried by the proximal end and means permitting the introduction of a radiographic contrast liquid for inflating said inflatable annular portion and the removal of said radiographic contrast liquid to deflate said annular portion.

11. In a dilating catheter assembly, a first flexible tubular member formed of a flexible plastic material and serving as an inner catheter, a second flexible tubular member, said second tubular member encasing said first tubular member so that said first and second tubular members are coaxially aligned, said first and second tubular members having proximal and distal ends, said second tubular member having a balloon-shaped portion formed therein adjacent the distal end and a fitting carried by the proximal ends for permitting insertion and withdrawal of a fluid for inflating and deflating the balloon-shaped portion of the second tubular member.

12. An assembly as in claim 11 in which the first and second tubular members are formed of a heat-shrinkable plastic.

13. An assembly as in claim 12 wherein the distal ends of the first and second tubular members are bonded together to form a fluid-tight adhesive free seal.

14. An assembly as in claim 12 wherein the first and second annular members are formed so that an annular flow passage extends therebetween from the proximal ends to the inflatable annular portion.

15. An assembly as in claim 12 in which the inflatable annular portion is integral with the second tubular member.

16. An assembly as in claim 15 in which the inflatable annular portion has a wall thickness substantially less than the wall thickness of the second tubular member.

17. In combination, a dilating catheter assembly having proximal and distal ends, the dilating catheter assembly having an inflatable annular member near the distal end and having a first flow passage leading from the proximal end to the inflatable annular member, a removable tubular member disposed within the dilating catheter assembly and providing a second flow passage extending from the proximal end into the inflatable annular member and means for introducing a radiographic contrast liquid into the inflatable annular member by using one of said first and second flow passages to introduce the liquid into the inflatable annular member to fill the same and to thereby force all air out of the inflatable annular member through the other of the first and second flow passages.

18. A combination as in claim 17 wherein the second tubular member is removed after the inflatable annular member has been inflated.

19. A combination as in claim 17 wherein said removable tubular member is in the form of a flushing tube and wherein the radiographic contrast liquid is introduced into the inflatable annualar member through the flushing tube.

20. In a method for inflating a dilating catheter assembly having a first tubular member with an inflatable annular portion near the distal end thereof and having a first flow passage leading from the proximal end to the inflatable annular portion, placing a second tubular member in said first flow passage of said first tubular member forming a seal between the first and second tubular members between the inflatable annular portion and the distal ends and providing a second flow passage extending from the inflatable annular portion to the proximal end, introducing a radiographic contrast liquid into one of said first and second flow passages to fill the inflatable annular portion with the radiographic contrast liquid and to thereby force air out of the inflatable annular portion and out through the other of the first and second flow passages.

21. A method as in claim 20 wherein the radiographic contrast fluid is introduced through the second flow passage provided in the tubular member.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 4,323,071

DATED : April 6, 1982

INVENTOR(S) : John B. Simpson et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the title page, Related U. S. Application Data:
Line 63; delete the year "1984" and insert --1980--.

Claim 2, Column 13, line 43, after the word "assembly, delete [of said guiding catheter assembly]

Claim 2, Column 13, line 45, after the word "member", insert -of said guiding catheter assembly --

Claim 5, Column 13, line 66, after the word "assembly", delete [surrounding said second tubular member of said dilating catheter assembly]

Claim 5, Column 14, line 16, delete the word "contract" and substitute --contrast--

Claim 10, Column 14, line 49, delete the first appearance of "and".

Claim 20, Column 16, line 17, insert a comma after the word "member"

Claim 20, Column 16, line 19, after the word "ends", insert a comma and delete the word "and";

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 4,323,071 Page 2 of 2

DATED : April 6, 1982

INVENTOR(S) : John B. Simpson et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Claim 20, Column 16, line 21, after the word "end,", insert the word --and--

Claim 20, Column 16, line 24, after the word "liquid", delete the words [and to] ; after the word thereby, delete the word [force] and substitute the word --forcing--.

Signed and Sealed this

Third Day of May 1983

[SEAL]

Attest:

GERALD J. MOSSINGHOFF

Attesting Officer *Commissioner of Patents and Trademarks*

REEXAMINATION CERTIFICATE (1289th)

United States Patent [19] [11] **B1 4,323,071**

Simpson et al. [45] Certificate Issued **May 29, 1990**

[54] **VASCULAR GUIDING CATHETER ASSEMBLY AND VASCULAR DILATING CATHETER ASSEMBLY AND A COMBINATION THEREOF AND METHODS OF MAKING THE SAME**

[75] Inventors: **John B. Simpson**, Menlo Park; **Edward W. Robert**, Los Altos, both of Calif.

[73] Assignee: **Advanced Cardiovascular Systems, Inc.**

Reexamination Request:
No. 90/001,327, Sep. 10, 1987
No. 90/001,386, Dec. 1, 1987

Reexamination Certificate for:

Patent No.:	**4,323,071**
Issued:	**Apr. 6, 1982**
Appl. No.:	**151,175**
Filed:	**May 19, 1980**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 123,713, Feb. 21, 1984, abandoned, which is a continuation of Ser. No. 899,061, Apr. 24, 1978, abandoned.

[51] **Int. Cl.**[5] **A61M 25/00**
[52] **U.S. Cl.** **128/343**; 604/96
[58] **Field of Search** 128/343, 344, 348.1; 604/96–103

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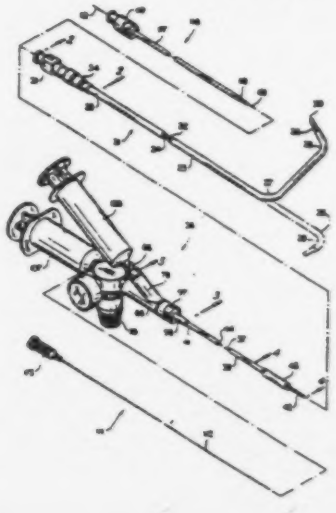
Primary Examiner—Dalton L. Truluck

[57] **ABSTRACT**

A combination guiding catheter assembly and a dilating catheter assembly. The guiding catheter assembly includes a first flexible tubular member formed of a material which has a low coefficient of friction and a second flexible tubular member encasing said first tubular member so that the first tubular member fits tightly in the second tubular member. The combined first and second tubular members have proximal and distal ends with a fitting mounted on the proximal end. The dilating catheter assembly includes a flexible tubular member. The tubular member of the dilating catheter assembly having proximal and distal ends and an inflatable annular portion formed integral with the tubular member of the dilating catheter assembly near the distal end thereof. A fitting is mounted on the proximal end of the tubular member of the dilating catheter assembly. The dilating catheter assembly is disposed within the guiding catheter assembly. An inflator is provided for inflating and deflating the inflatable annular portion.



REEXAMINATION CERTIFICATE ISSUED UNDER 35 U.S.C. 307

THE PATENT IS HEREBY AMENDED AS INDICATED BELOW.

Matter enclosed in heavy brackets [ ] appeared in the patent, but has been deleted and is no longer a part of the patent; matter printed in italics indicates additions made to the patent.

AS A RESULT OF REEXAMINATION, IT HAS BEEN DETERMINED THAT:

The patentability of claims 1–4, 6, 8, 9 and 11–16 is confirmed.

Claims 5, 10, 17, 20 and 21 are determined to be patentable as amended.

Claims 7, 18 and 19, dependent on an amended claim, are determined to be patentable.

New claims 22–52 are added and determined to be patentable.

5. In a combination of a guiding catheter assembly and a dilating catheter assembly, a guiding catheter assembly comprising a first flexible tubular member formed of a material which has a low coefficient of friction below 0.05, a second flexible tubular member encasing said first tubular member so that the first tubular member fits tightly in the second tubular member to combine the first and second tubular members, said combined first and second tubular members having proximal and distal ends and a fitting mounted on the proximal end, the dilating catheter assembly comprising first and second tubular members, said [first] *second* tubular member of said dilating catheter assembly surrounding said [second] *first* tubular member of said dilating catheter assembly surrounding said second tubular member of said dilating catheter assembly, said [first] *second* tubular member of said dilating catheter assembly having proximal and distal ends and an inflatable annular portion formed integral with the tubular member near the distal end thereof, means forming a fluid-tight seal between the first and the second tubular members of the dilating catheter assembly in a region between the inflatable annular portion and the distal ends of the first and second tubular members of the dilating catheter assembly, a fitting mounted on the proximal ends of the first and second tubular members of the dilating catheter assembly, means forming a fluid passageway from the proximal ends of the first and second tubular members of the dilating catheter assembly extending into the inflatable annular portion, said dilating catheter assembly being disposed within said guiding catheter assembly and means for inflating said inflatable annular portion with a radiographic contrast liquid.

10. In a dilating catheter assembly for use with a radiographic contrast liquid, a flexible tubular member [and] having proximal and distal ends, said tubular member having an inflatable annular portion formed integral therewith adjacent the distal end and a fitting carried by the proximal end and means permitting the introduction of a radiographic contrast liquid for inflating said inflatable annular portion and the removal of said radiographic contrast liquid to deflate said annular portion.

17. [In combination, a] *An elongated* dilating catheter [assembly] having:

proximal and distal ends, [the dilating catheter assembly having]

an inflatable annular member near the distal end [and having]

a first flow passage *therein* leading from the proximal end *of the catheter* to the *interior of the* inflatable annular member,

a removable [tubular member] *vent tube* disposed within *the first flow passage of* the dilating catheter [assembly and providing] *and extending into the interior of the inflatable annular member, said removable vent tube having* a second flow passage extending [from the proximal end into] *therethrough in fluid communication with the interior of* the inflatable annular member, and

means for introducing a radiographic contrast liquid into the inflatable annular member by using one of said first and second flow passages to introduce the liquid into the *interior of the* inflatable annular member to fill the same and to thereby force all air out of the *interior of the* inflatable annular member through the other of the first and second flow passages.

20. [In a] *A* method for inflating [a] *an elongated* dilating catheter [assembly] having a first tubular member with an inflatable annular portion near the distal end thereof and having a first flow passage leading from the proximal end to the *interior of the* inflatable annular portion, *said method comprising:*

placing a second tubular member in said first flow passage of said first tubular member,

forming a seal between the first and second tubular members between the inflatable annular portion and the distal ends [and providing];

inserting a removable vent tube having a second flow passage *into the first flow passage with the distal end thereof* extending [from] *into* the *interior of the* inflatable annular portion [to the proximal end,];

introducing a radiographic contrast liquid into one of said first and second flow passages to fill the inflatable annular portion with the radiographic contrast liquid and to thereby force air out of the *interior of the* inflatable annular portion and out through the other of the first and second *flow* passages; *and*

removing the vent tube from the first flow passage.

21. A method as in claim 20 wherein the radiographic contrast fluid is introduced through the second flow passage provided in the [tubular member] *vent tube.*

22. The dilating catheter assembly of claim 10 wherein the inflatable annular element comprises a crystalline plastic material and is preformed into the desired inflated shape by heating an area of the tubular member which forms the inflatable annular element to a temperature above the crystalline melting point thereof, subjecting the heated area to internal pressure to expand the heated material into the desired inflated shape, and maintaining the internal pressure thereof while cooling the expanded portion to a temperature below the crystalline melting point of the plastic material.

23. The dilating catheter of claim 10 including an inner member with the distal end of the tubular member bonded thereto.

24. The dilating catheter of claim 23 wherein the inflatable annular portion is preformed to inflate to a desired size.

25. The dilating catheter of claim 10 wherein the inflatable annular portion is preformed to inflate to a desired elongated shape to facilitate the dilation of a stenotic region of a patient's artery.

26. The dilating angioplasty catheter of claim 25 wherein the inflated annular portion is generally cylindrically shaped.

27. The dilating angioplasty catheter of claim 25 wherein the flexible plastic tubular member is formed of heat shrinkable plastic.

28. The dilating angioplasty catheter of claim 25 wherein the flexible plastic tubular member is formed of crystalline plastic material.

29. The dilating angioplasty catheter of claim 25 wherein the wall thickness of the inflatable annular portion is substantially less than the thickness of the adjacent unexpanded tubular member.

30. The dilating catheter of claim 25 wherein the balloon is formed of crystalline plastic material and is preformed into the desired inflated shape by heating the desired area of the second tubular member to a temperature above the crystalline melting temperature thereof, subjecting the heated portion to internal pressure to expand the heated portion into the desired inflated shape and then cooling the expanded portion to a temperature below the crystalline melting temperature while maintaining the expanded portion in the expanded condition.

31. The dilating catheter of claim 10 wherein the inflatable annular portion is proximal to the distal end of the tubular member.

32. The dilating catheter of claim 14 wherein the proximal ends of the inner and outer members are fixed to an adapter with means to direct inflation fluid through the annular flow passage between the inner and outer tubular members.

33. The dilating catheter assembly of claim 11 wherein the balloon-like element comprises crystalline plastic material and is preformed into the desired inflated shape by heating an area of the second tubular member which forms the balloon-like portion to a temperature above the crystalline melting point thereof, subjecting the heated area to internal pressure to expand the heated material into the desired inflated shape, and maintaining the internal pressure thereof while cooling the expanded portion to a temperature below the crystalline melting point of the plastic material.

34. The dilating catheter of claim 11 wherein the balloon-shaped portion is preformed to inflate to a desired elongated shape.

35. The dilating angioplasty catheter of claim 34 wherein the second tubular member is formed of heat shrinkable plastic.

36. The dilating angioplasty catheter of claim 34 wherein the first tubular member is formed of heat shrinkable plastic.

37. The dilating angioplasty catheter of claim 34 wherein the first tubular member is formed from crystalline plastic material.

38. The dilating angioplasty catheter of claim 34 wherein the second tubular member is formed of crystalline plastic material.

39. The dilating angioplasty catheter of claim 34 wherein the elongated inflatable balloon has a generally cylindrical shape.

40. The dilating angioplasty catheter of claim 34 wherein the elongated balloon is from about 1 to 2 cm long.

41. The dilating angioplasty catheter of claim 34 wherein the elongated balloon has a wall thickness of about 0.002 to 0.004 inches.

42. The dilating angioplasty catheter of claim 34 wherein the elongated balloon has an inflated diameter of about 4 to 5 times the original diameter of the tubular member adjacent thereto.

43. The dilating angioplasty catheter of claim 34 having a third removable tubular member disposed between the first and second tubular members extending from the proximal ends thereof to the interior of the balloon to discharge air from the interior of the balloon when inflating fluid is introduced thereinto.

The dilating angioplasty catheter of claim 34 wh[illegible]in the inflatable balloon is formed by heating the portion of the tubular member which forms the inflatable balloon, subjecting the heated portion to internal pressure to expand the heated portion to form the annular element into the desired inflated shape and then cooling the expanded portion while maintaining it in the expanded condition.

45. The dilating angioplasty catheter of claim 44 wherein the portion of the tubular member which forms the inflatable balloon is heated above the crystalline melting point of the plastic material forming the tubular member.

46. The dilating angioplasty catheter of claim 45 wherein the expanded portion is cooled to a temperature below the crystalline melting point of the plastic material while the expanded portion is maintained in the expanded condition.

47. The dilating angioplasty catheter of claim 44 wherein the expanded portion of the tubular member is expanded to a diameter of about 4 to 5 times the original diameter of the tubular member.

48. The dilating angioplasty catheter of claim 44 wherein the expanded portion is expanded to its elastic limit during formation.

49. The dilating angioplasty catheter of claim 44 wherein the expanded portion has an outside diameter of about 0.12 to 0.14 inch.

50. The dilating catheter of claim 34 wherein the balloon-shaped portion is preformed to inflate to a desired size to facilitate the dilation of a stenotic region of a patient's artery.

51. The dilating catheter of claim 11 wherein the distal ends of the inner and outer tubular members are bonded together.

52. The dilating catheter of claim 11 wherein the balloon-shaped portion is proximal to the distal end of the outer tubular member.

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